

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 RESPONDENT**



# 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

In 1996, the World Health Organization (“W.H.O.”) declared a worldwide pandemic of Multivector Hepatic Viral Disease (“M.H.V.D.”), a highly contagious, deadly disease with no known cure. A W.H.O. Special Panel reported in 1997 that basic sanitation was the only current defence against the disease, and urged scientists to develop a vaccine.

Senhava is a small, ethnically-diverse developing nation, economically reliant on foreign aid, natural resources and tourism. Over 20% of its population is infected with M.H.V.D..

Kuraca, a large industrial country, has one of the world’s leading biotechnology industries. Megaceutical Corporation, a multinational pharmaceutical company based in Kuraca, leads the development of an M.H.V.D. vaccine, and has conducted vaccine tests in Senhava through Megaceutical-Senhava, a Senhavan company majority owned by Senhavans. Dr. Yukawa-Lopez, a Kuracan physician and the world’s leading M.H.V.D. expert, headed Megaceutical-Senhava’s M.H.V.D. vaccine development project in Senhava. George Smith, a Nemini, was hired by the Kuracan Medical Product Regulation Agency to monitor the operations of Megaceutical-Senhava.

Preliminary vaccine trials indicated substantial improvement in 28 of 30 infected volunteers. Two volunteers developed an unusual, disabling asthma. Research was accelerated to the clinical trial stage, using a vaccine variant thought to be safer. In June, Senhava approved Megaceutical-Senhava’s application to conduct trials amongst high risk groups who would benefit most from it, and Megaceutical made an advance payment of Euros 2,000,000. Megaceutical-Senhava’s trial protocol provided, *inter alia*, for the

informed consent of all test subjects, with special procedures for children and those unable to read the form.

In early August, the Agency's Administrator verbally warned Megaceutical's President to terminate the trial, lest unspecified human rights be violated. She threatened government refusal to approve supplies of necessary biological material for any M.H.V.D. trials should Megaceutical attempt to proceed. The Administrator relied on the decision of a Kuracan ethical review board which reviewed the Megaceutical-Senhava protocol, and reports compiled by Smith. Consequently, Dr. Yukawa-Lopez resigned, and on 10 August Megaceutical-Senhava notified the Senhavan government of its decision to halt the trial. On August 12, Senhava arrested Smith for interfering with Senhavan public health measures.

On August 15 Senhava notified Kuraca that attempts to halt the trial amounted to "cultural imperialism" and an unacceptable extraterritorial application of Kuracan law. It warned that, unless obstructions were withdrawn, Senhava would compel Megaceutical-Senhava to proceed with the trial. Kuraca responded, claiming that Senhava interfered with Kuraca's right to regulate its corporations, and demanded the release of Smith. Further diplomatic notes were exchanged reasserting the validity of each State's conduct, without resolution of the dispute.

On September 16, Senhava declared an M.H.V.D. public health emergency, and in accordance with its legislation ordered Megaceutical-Senhava to proceed with the trial or face penalties. Megaceutical refused to allow Megaceutical-Senhava to comply with the order, and on September 21, Senhava shut down the Megaceutical-Senhava's offices, and levied fines. Senhava notified Kuraca that Kuracan obstruction of the trial was unacceptable under international law, and that the use of Kuracan "muscle" violated Senhava's sovereign rights to govern its own commerce and protect public health. Each state recalled its

ambassador, suggesting an imminent break in relations. In October 1999, after meeting with an ad hoc group of Nobel Peace Laureates, the respective Presidents issued a joint statement referring the dispute to the International Court of Justice in order not to risk rupturing the historic good relations between their nations.

Both States are members of the United Nations and the World Health Organization, and parties to the Vienna Convention on the Law of Treaties, Convention on the Rights of the Child, 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. The dispute appears before this Court by a 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 Nemin is an indispensable party to the case.
4. Whether Senhava acted in accordance with international law when it detained George Smith.
5. Whether Kuracan National Health Law 1006 breaches Kuraca's duty of non-intervention and infringes Senhavan sovereignty.
6. Whether Kuraca has breached the right to health, the right to life and the prohibition against cruel, inhuman and degrading treatment.
7. Whether Senhava acted in accordance with international law in its treatment of Megaceutical-Senhava.
8. Whether Megaceutical's advance payment of 2 millions Euros must be refunded.
9. Whether Kuraca must pay reparations for Senhava's public health costs

## Summary of Pleadings

Both Kuraca and Senhava have made declarations under Article 36(2) of the Statute of the International Court of Justice (“Statute”). Senhava has agreed to come before the Court, subject to preliminary objections to jurisdiction. Senhava denies that the Court has jurisdiction over this dispute.

By virtue of reciprocity, Senhava relies on the two reservations in Kuraca’s declaration accepting jurisdiction: the domestic jurisdiction reservation and the multilateral treaty reservation. The domestic jurisdiction reservation allows Senhava to determine conclusively that the dispute is within its domestic jurisdiction. If the Court determines that the reservation is invalid, it is not severable, leaving Kuraca’s entire declaration invalid. Alternatively, if the reservation is valid but its invocation reviewable, the Court need only consider whether Senhava has invoked it in good faith. Given that the subject matter of the dispute exclusively concerns the public health of Senhavan citizens on Senhavan territory, the Court should uphold Senhava’s determination and decline jurisdiction. Under the multilateral treaty reservation, Senhava contends that all parties to treaties affected by the decision must be present before the Court can accept jurisdiction. Alternatively, parties specifically affected must be present and they are not.

Kuraca has no standing to bring the claim in respect of Megaceutical-Senhava (“M-S”) or George Smith. Under international law, M-S is a national of Senhava and Kuraca lacks standing to make a claim on behalf of Kuracan interests in M-S. Smith is not a national of Kuraca, and his status as an independent contractor does not entitle Kuraca to exercise diplomatic protection. Kuraca may not claim standing on the basis that Senhava has breached obligations owed *erga omnes*. Senhava has not breached any such obligation, and even if it

has, no generalised right of standing attaches. A further bar to admissibility is the absence of Nemin, whose interests constitute the very subject matter for decision.

Kuracan Health Law 1006 (“Law 1006”) offends the *jus cogens* duty of non-intervention and is an impermissible exercise of extraterritorial jurisdiction. Law 1006 offends the rule of reasonableness and constitutes foreign state compulsion.

In obstructing the M.H.V.D. vaccine trials, Kuraca breached the duty to maintain peace and security. Kuraca breached the right to health, the right to life and the prohibition against cruel, inhuman and degrading treatment. Informed consent is at most an ethical obligation which is not customary international law. If an international law obligation to obtain informed consent is said to exist, the Court must allow for economic and cultural variation. The trial as proposed is consistent with that obligation in Senhava . The trial does not violate the principle of non-discrimination.

Senhava’s treatment of M-S is justified by a state of necessity and in accordance with customary international law. Smith is detained as a threat to national security, pursuant to a state of emergency. Senhava has probable cause to suspect him of interfering with public health measures.

Kuraca must repeal or alter Law 1006 to the extent that it impedes the vaccine trials. Kuraca must also pay reparations to Senhava for foreseeable loss caused by the breach. This includes the public health costs of treating M.H.V.D. victims. Senhava is not liable to refund Megaceutical’s 2 million Euro advance payment as the obstruction of the vaccine trials is Kuraca’s responsibility. The Court cannot make orders concerning Smith which are in the nature of a *habeas corpus*, nor function as a Court of criminal appeal.

## Written Pleadings

### I. THE COURT HAS NO JURISDICTION

Judicial restraint in exercising jurisdiction is a feature of this Court.<sup>1</sup> No case can proceed without the consent of all parties, which, out of respect for their sovereignty, “must be proved up to the hilt”.<sup>2</sup> Senhava’s consent to the compulsory jurisdiction of the Court is vitiated by its invocation of Kuraca’s two reservations. Moreover, an indispensable third party, Nemin, has not given the necessary consent to the Court’s jurisdiction. There is no basis for prorogated jurisdiction, which is limited to exceptional circumstances of clear, unqualified consent to the Court’s jurisdiction.<sup>3</sup>

#### A. The Court’s compulsory jurisdiction is precluded by Kuraca’s self-judging reservation, as invoked by Senhava

##### 1. The reciprocal invocation of this reservation is valid and non-reviewable

A reservation to the declaration of the compulsory jurisdiction of the International Court of Justice is qualified by the principle of reciprocity,<sup>4</sup> which enables the State with a wider acceptance of jurisdiction to rely upon the reservations to the acceptance made by the other party.<sup>5</sup> Senhava is therefore entitled to invoke Kuraca’s reservation of matters

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<sup>1</sup> ANAND, *INTERNATIONAL COURTS AND CONTEMPORARY CONFLICTS* 198-9 (1974).

<sup>2</sup> LAUTERPACHT, *THE DEVELOPMENT OF INTERNATIONAL LAW BY THE INTERNATIONAL COURT* 91 (2d ed., 1958); Advisory Opinion No. 5, Status of Eastern Carelia, 1923 P.C.I.J. (ser. B) No. 5, at 27 (July 23).

<sup>3</sup> BROWNLIE, *PRINCIPLES OF INTERNATIONAL LAW* 724 (5<sup>th</sup> ed. 1998); *Compromis*, para. 33.

<sup>4</sup> STATUTE OF THE INTERNATIONAL COURT OF JUSTICE art. 36, para. 2; Ende, *Reaccepting the Compulsory Jurisdiction of the International Court of Justice: A Proposal for a New United States Declaration*, 16 WASH. L. REV. 1145, 1152 (1986).

<sup>5</sup> *Interhandel (Switz. v. U.S.)*, 1959 I.C.J. 6, 23 (Mar. 21).

“essentially within the domestic jurisdiction of Kuraca as determined by Kuraca”.<sup>6</sup> In its opportunities to consider the validity of the self-judging reservation, this Court has never regarded it as invalid, nor arrogated to itself the right to review the determination of the State relying on the reservation.<sup>7</sup> Significantly, States themselves have not objected to the making of such reservations at the time declarations are lodged, and have acquiesced in their use.<sup>8</sup> Self-judging reservations have therefore come to be accepted as *prima facie* valid, and should be accorded their express meaning. Senhava’s determination is thus not subject to review or approval by any tribunal.<sup>9</sup> Implying an obligation of good faith or reasonableness is inconsistent with the express wording of the reservation, and inconsistent with the practice of this Court.<sup>10</sup> There are no clear standards for assessing the *bona fides* of a determination<sup>11</sup> and the implication is contrary to the intention of the reserving State, as manifested in the plain meaning of the reservation.<sup>12</sup>

**2. If Senhava’s determination is reviewable, it has been made in good faith**

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<sup>6</sup> *Compromis*, Annex D.

<sup>7</sup> ROSENNE, *THE LAW AND PRACTICE OF THE INTERNATIONAL COURT* 398-9 (1985); SHIHATA, *THE POWER OF THE INTERNATIONAL COURT TO DETERMINE ITS OWN JURISDICTION* 284-97 (1965).

<sup>8</sup> Crawford, *The Legal Effect of Automatic Reservations to the Jurisdiction of the International Court*, 50 *BRIT Y.B. INT’L L* 63, 81, 85 (1979).

<sup>9</sup> Oral Argument of Mr Becker (*Switz. v. U.S.*), 1959 *I.C.J. Pleadings (Interhandel)* 452 (Oct. 12, 1957).

<sup>10</sup> Goldie, *The Connolly Reservation: A Shield for an Adversary*, 9 *UCLA L. REV.* 277, 292-3 (1962); *Interhandel*, *supra* n. 5 (diss. op. Judge Lauterpacht).

<sup>11</sup> *Certain Norwegian Loans (Fr. v. Nor.)*, 1957 *I.C.J.* 9, 52-4 (July 6) (diss. op. Judge Lauterpacht).

<sup>12</sup> *Interhandel*, *supra* n. 5, 57-8 (sep. op. Judge Spender); *Certain Norwegian Loans*, *supra* n. 11, 67 (diss. op. Judge Guerrero); Crawford, *supra* n. 8, 67.

If the Court holds that it can review the *bona fides* of Senhava's determination, the question is whether the determination of domestic jurisdiction is arbitrary or so manifestly unreasonable as to constitute an *abus de droit* from which the Court must protect itself. The Court is not called upon to assess whether it would have made the same decision, but whether the decision is within the penumbra of possible good faith decisions that could have been made. The Court must allow a "margin of appreciation" for Senhava's decision, and not overturn it unless it is manifestly incorrect.<sup>13</sup> It is reasonable for Senhava to determine that the issues surrounding the vaccine trial are essentially within domestic jurisdiction, as they exclusively concern the public health of its citizens within its territory. Although this Court has held that treaty regulation removes a matter from being "exclusively within domestic jurisdiction", the existence of relevant treaties does not make it unreasonable for Senhava to determine these matters are "essentially" domestic.<sup>14</sup> The determination is also consistent with the meaning of "essentially" domestic in the U.N. Charter, which expanded the reserved domain to allow for the protection of smaller nations and to secure support for the incorporation of human rights.<sup>15</sup>

**3. If the automatic reservation is invalid, Kuraca's entire declaration is invalid**

There are two grounds upon which the self-judging reservation may be held invalid by this Court. Firstly, because the performance of the undertaking is conditional upon the unilateral determination of the party who is to perform it, it is an illusory obligation and not

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<sup>13</sup> Fitzmaurice, *The Law and Procedure of the International Court of Justice, 1954-9*, 35 BRIT. Y.B. INT'L L. 183, 213-4 (1959).

<sup>14</sup> Interpretation of Peace Treaties with Bulgaria, Hungary and Romania, 1950 I.C.J. 65, 112 (Mar. 30) (diss. op. Judge Krylov).

<sup>15</sup> RAJAN, UNITED NATIONS AND DOMESTIC JURISDICTION 78 (2d ed. 1961).

cognisable as legally binding.<sup>16</sup> Second, in preventing the Court from reviewing the circumstances of its invocation, the reservation is inconsistent with the general international law principle of *competence de la competence*, and Article 36(6) of the Statute of the Court.<sup>17</sup>

If the reservation is for these reasons invalid, it cannot be severed from the declaration, and Kuraca's entire declaration is invalid.<sup>18</sup> That States regard reservations as an integral part of their acceptance to the Court's jurisdiction, without which the latter would never be given, is evidenced plainly in the history of Article 36(2) and the actions and declared policies of States.<sup>19</sup> Reservations define the scope of the obligation undertaken, and there is a "close and necessary link between a jurisdictional clause and reservations to it".<sup>20</sup> The drafting history of the original self-judging reservation of the United States clearly indicates that it was central to that State's acceptance of the Court's compulsory jurisdiction.<sup>21</sup> To sever the reservation while upholding the declaration would radically transform the extent of the obligation of judicial settlement, contrary to the fundamental principle that jurisdiction is wholly dependent upon consent.

Senhava further asserts that if the Court were to reject previous authority and sever the self-judging element of the reservation from Kuraca's declaration, it would still be bound by

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<sup>16</sup> *Certain Norwegian Loans*, *supra* n. 11, 48 (sep. op. Judge Lauterpacht).

<sup>17</sup> *Interhandel*, *supra* n. 5, 56 (sep. op. Judge Spender), 76 (diss. op. President Klaestad), 92-3 (diss. op. Judge Armand-Ugon), 101-16 (diss. op. Judge Lauterpacht).

<sup>18</sup> *Interhandel*, *supra* n. 5, 101 (diss. op. Judge Lauterpacht).

<sup>19</sup> *Id.*

<sup>20</sup> *Aegean Sea Continental Shelf (Greece v. Turk.)*, 1978 I.C.J. 3, 32 (Dec. 19).

<sup>21</sup> Wilcox, *The United States Accepts Compulsory Jurisdiction*, 40 AM. J. INT'L L. 699, 715 (1946).

Article 2(7) of the U.N. Charter, where members are not required to submit to settlement matters “essentially within the domestic jurisdiction”. The domestic nature of the dispute is a conclusive objection to the Court’s jurisdiction, even in the absence of a reservation.<sup>22</sup>

**B. The Court cannot exercise jurisdiction in the absence of indispensable third parties**

Kuraca’s submission requires the Court to determine the rights and obligations of a third State, Nemin, without its consent.<sup>23</sup> As Kuraca has requested the Court to order the release of Nemin’s national, George Smith, Nemin’s interest forms “the very subject matter of the decision”.<sup>24</sup> This is because an injury to a citizen is an injury to the State at international law.<sup>25</sup> The Court is unable to compel Nemin’s presence, and its refusal to intervene in the dispute prevents the Court from exercising jurisdiction.<sup>26</sup>

**C. Senhava’s invocation of Kuraca’s multilateral treaty reservation prevents the Court from exercising jurisdiction in the absence of affected parties**

**1. The Court lacks jurisdiction because all parties to the affected treaties are not parties to the case**

By virtue of reciprocity,<sup>27</sup> Senhava invokes Kuraca’s multilateral treaty reservation. Because Senhava has not specially agreed to jurisdiction, the Court may exercise jurisdiction only if all parties to the treaties affected by the decision of the Court are also parties to the

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<sup>22</sup> KELSEN, *PRINCIPLES OF INTERNATIONAL LAW* 784-5 (1952); Briggs, *Reservations to the Acceptance of the Compulsory Jurisdiction of the International Court of Justice*, 93 *RECUEIL DES COURS* 229, 311 (1958).

<sup>23</sup> *Certain Phosphate Lands in Nauru (Nauru v. Austl.)*, 1992 I.C.J. 240, 259-62 (June 26).

<sup>24</sup> *Monetary Gold Removed from Rome in 1943 (Italy v. Fr., U.K., U.S.)*, 1954 I.C.J. 19, 32 (June 15).

<sup>25</sup> VATTEL, *THE LAW OF NATIONS* (Chitty ed., 1834); BROWNLIE, *supra* n. 3, 521.

<sup>26</sup> *East Timor (Port. v. Austl.)*, 1995 I.C.J. 90, 101 (June 30).

<sup>27</sup> *Certain Norwegian Loans*, *supra* n. 11, 24.

case. A declaration “must be interpreted as it stands, having regard to the words actually used”.<sup>28</sup> Senhava relies on the reservation’s emphasis on “all parties” to the “treaty affected” to require the presence of all parties to the five multilateral treaties invoked by Kuraca.<sup>29</sup> Despite some difficulty of implementation, this interpretation is consistent with the principle that a State is entitled to attach any reservation, however drastic, not incompatible with the provisions of the Statute.<sup>30</sup> This Court has not rejected this interpretation.<sup>31</sup> Significantly, the expanded use of similar reservations requiring the presence of “all parties”<sup>32</sup> indicates States’ acceptance of the reservation despite its consequences.

**2. Alternatively, the Court lacks jurisdiction because State parties specifically affected are not present before the Court**

Because the reservation contemplates “parties affected” rather than States with a legal right in the proceedings,<sup>33</sup> Senhava identifies, as affected, other treaty parties that accommodate the “laboratories, public health agencies, and pharmaceutical companies from many parts of the world [that] have been working to understand the disease and to develop means to prevent its spread.”<sup>34</sup> Any determination by the Court on the validity of foreign intervention in vaccine trials will materially affect other State parties’ research.

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<sup>28</sup> *Anglo-Iranian Oil Co. (U.K v. Iran)*, 1952 I.C.J. 93, 105 (July 22).

<sup>29</sup> MAUS, LES RÉSERVES DANS LES DÉCLARATIONS D’ACCEPTATION DE LA JURIDICTION OBLIGATOIRE DE LA COUR INTERNATIONALE DE JUSTICE (1959).

<sup>30</sup> *Briggs*, *supra* n. 22, 232.

<sup>31</sup> *Military and Paramilitary Activities (Jurisdiction) (Nicar. v. U.S.)*, 1984 I.C.J. 392 (May 10).

<sup>32</sup> *Id.* 468 (sep. op. Judge Mosler).

<sup>33</sup> *Id.* 422 (judgment).

<sup>34</sup> *Compromis*, para. 6.

Clearly, even if only one other treaty party is found to be “affected”, the multilateral treaty reservation takes full effect.<sup>35</sup> Nemin is a member of all the treaties relied on by Kuraca, and its interests will necessarily be affected because the Court’s determination must include the question of the validity of Senhava’s detention of Smith, a Nemin national.

**3. The multilateral treaty reservation deprives the Court of jurisdiction over all aspects of the dispute .**

Furthermore, if the Court identifies that affected parties are not present, the correct interpretation of the reservation operates to bar the Court from adjudicating any aspect of the dispute.<sup>36</sup> Kuraca’s dispute with Senhava has arisen under the human rights obligations of five multilateral treaties, and the existence of similar customary obligations cannot circumvent the reservation.<sup>37</sup> As the Court’s jurisdiction is barred, it cannot apply other sources of law. Senhava’s acceptance of the Court’s jurisdiction is therefore reserved in this claim.

**II. THE CLAIM IS INADMISSIBLE**

**A. Kuraca has no standing**

The existence of a legal interest is “the indispensable basis of a justiciable dispute”.<sup>38</sup> Senhava’s conduct has not touched a legally protected interest of Kuraca or its nationals, and Kuraca has no standing to institute proceedings.<sup>39</sup>

**1. Kuraca has no legal interest in Senhava’s actions towards Megaceutical-**

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<sup>35</sup> *Military and Paramilitary Activities (Merits)*, 1986 I.C.J. 14, 34 (June 27).

<sup>36</sup> *Id.* 218 (diss. op. Judge Oda); 533 (diss. op. Judge Jennings).

<sup>37</sup> *Id.* 217 (diss. op. Judge Oda).

<sup>38</sup> *Northern Cameroons (Cameroon v. U.K.)*, 1963 I.C.J. 15, 46 (Dec. 2) (sep. op. Judge Wellington Koo).

<sup>39</sup> Jennings, *General Course on Principles of International Law*, II RECUEIL DES COURS 327, 507 (1957).

## Senhava

Megaceutical-Senhava (M-S) is a Senhavan national under international as well as Senhavan law. Its incorporation, headquarters and operations are all located in Senhava, thus satisfying the internationally-recognised prerequisites of incorporation and domicile for establishing nationality.<sup>40</sup> Although the nationality of shareholders is largely irrelevant to international law,<sup>41</sup> Senhavan nationals also enjoy a majority equity ownership in M-S. While the actions of M-S are subject to a shareholder agreement with Megaceutical Corporation (MC), it would be an unacceptable extension of international law to allow such an agreement to determine nationality.<sup>42</sup> Senhava's regulation of M-S is therefore a valid exercise of sovereignty.<sup>43</sup>

Kuraca also lacks standing to bring an action on behalf of Kuracan interests in M-S. States possess no general right to afford diplomatic protection to their nationals who hold shares in a foreign company.<sup>44</sup> While an artificial exception to this principle was mooted in *Barcelona*, this right was restricted to a defunct company, or one without legal protection. Moreover, subsequent shareholder actions have only been brought under express treaty

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<sup>40</sup> Standard Oil Co. of New York (U.S. v. F.R.G.), 7 R.I.A.A. 301 (Gen. Cl. Comm'n. 1926); *Barcelona Traction, Light and Power Co. Ltd. (Belg. v. Spain)*, 1972 I.C.J. 4, 42 (Feb. 5); AMERICAN LAW INSTITUTE, 2 RESTATEMENT OF THE LAW THIRD: FOREIGN RELATIONS LAW OF THE UNITED STATES paras. 213, 702 (1987) [hereinafter THIRD RESTATEMENT]; BORCHARD, THE DIPLOMATIC PROTECTION OF CITIZENS ABROAD, 617-18 (1970 ed., 1915).

<sup>41</sup> *Barcelona*, *supra* n. 40, 42, THIRD RESTATEMENT, *supra* n. , paras. 213, 713.

<sup>42</sup> *Barcelona*, *supra* n. 40, 42; Harris, *The Protection of Companies in International Law in the Light of the Nottebohm Case*, 18 INT'L & COMP. L.Q. 275, 297 (1969).

<sup>43</sup> BROWNLIE, *supra* n. 3, 291.

<sup>44</sup> *Barcelona*, *supra* n. 40, 92-3.

provisions.<sup>45</sup>

## 2. Kuraca has no legal interest in the detention of George Smith

A State has no right to intervene in relations between another State and a national of a third State under customary international law.<sup>46</sup> Kuraca cannot extend diplomatic protection to Smith, as he is a citizen of Nemin and enjoys no “genuine connection” upon which to base a claim of Kuracan nationality.<sup>47</sup> There is no universally accepted basis for extending diplomatic protection beyond nationality.<sup>48</sup> Smith’s contract with the Kuracan Medical Product Regulation Agency (M.P.R.A.) is not a basis for diplomatic protection. Senhava’s consent to Smith’s presence cannot be construed as a special agreement to confer upon Kuraca a right of diplomatic protection, as such agreements require an explicit waiver of the rule of nationality.<sup>49</sup>

## 3. Kuraca cannot derive standing on behalf of the international community

While obligations *erga omnes* have been recognised by this Court, these are restricted to acts of aggression, genocide, slavery, and racial discrimination.<sup>50</sup> Modification of the content of such peremptory norms must be recognised by the international community as a whole.<sup>51</sup> It would be improper to characterise Senhava’s actions in protecting its population

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<sup>45</sup> *Elettronica Sicula S.p.A. (ELSI) (U.S. v. Italy)*, 1989 I.C.J. 15, 23 (July 20); *Barcelona*, *supra* n. 40, (sep. op. Judge Padilla Nervo).

<sup>46</sup> SCHWARZENBERGER, *INTERNATIONAL LAW* 355 (3d. ed. 1957).

<sup>47</sup> *Nottebohm (Liech. v. Guat.)* 1955 I.C.J. 4, 21-23 (Apr. 6); *Compromis*, para. 11.

<sup>48</sup> Leigh, *Nationality and Diplomatic Protection*, *INT’L & COMP. L.Q.* 453, 453-5 (1971).

<sup>49</sup> *Panevezys-Saldutiskis Railway (Est. v. Lith.)* 1939 P.C.I.J. (ser. A/B) No. 76, at 357 (Feb. 28).

<sup>50</sup> *Barcelona*, *supra* n. 40, 32; *East Timor*, *supra* n. 26, 102.

<sup>51</sup> *Barcelona*, *supra* n. 40, 47; HANNIKAINEN, *PEREMPTORY NORMS (JUS COGENS) IN INTERNATIONAL LAW* 270 (1988).

from a pandemic in such extreme and egregious terms. Moreover, this Court has never accepted an obligation *erga omnes* as conferring standing on an otherwise disinterested party.<sup>52</sup> Granting standing to Kuraca, which possesses no other interest in this matter, would amount to support for an *actio popularis*, which is not known to international law.<sup>53</sup> The right to an individual action on behalf of the legal community, especially when that State is seeking individual remedies, is inappropriate at international law.<sup>54</sup>

**B. Kuraca cannot bring an action as local remedies have not been exhausted**

This claim is also inadmissible because Senhava has not had an opportunity to redress the dispute by its own means, within the framework of its own domestic legal system.<sup>55</sup> Customary international law acknowledges the importance of flexibility in a State's design of local remedies.<sup>56</sup> There is no evidence that M-S or its individual shareholders have pursued a claim before the appropriate Senhavan tribunals. Kuraca is unable to discharge this burden of proof,<sup>57</sup> as M-S retains a legal personality and is competent to bring an action. Moreover, Smith's arrest stems from his interference with public health measures and it is only upon the conclusion of his trial that international law may act.<sup>58</sup>

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<sup>52</sup> *Report of the Commission to the General Assembly on the Work of its 32d. Session*, [1980] 2 Y.B. Int'l L. Comm'n. 32, A/CN.4/SER.A/1980/Add.1 (Part 2).

<sup>53</sup> *South West Africa (Eth. v. S. Afr.; Liber. v. S. Afr.)*, 1966 I.C.J. 6, 47 (July 18).

<sup>54</sup> Sacharier, *State Responsibility for Multilateral Treaty Violations: Identifying the 'Injured State' and its Legal Status* 35 NETH. INT'L L. REV. 273, 284 (1988).

<sup>55</sup> *Interhandel*, *supra* n. 5, 19.

<sup>56</sup> *ELSI*, *supra* n. 45, 15, 52.

<sup>57</sup> *Certain Norwegian Loans*, *supra* n. 11; *Documents of the 8<sup>th</sup> Session including the report of the Commission to the General Assembly*, [1956] 2 Y.B. Int'l L. Comm'n 173, A/CN.4/SER.A/1956/Add.1.; JOSEPH, NATIONALITY AND DIPLOMATIC PROTECTION: THE COMMONWEALTH OF NATIONS 6 (1969).

<sup>58</sup> *Finnish Shipowners Arbitration (Fin. v. U.K.)* 3 R.I.A.A. 1479, 1502-3 (1934).

### III. KURACAN ACTION UNDER HEALTH LAW 1006 OFFENDS THE FUNDAMENTAL PRINCIPLE OF NON-INTERVENTION

In promulgating and attempting to enforce Kuracan National Health Law 1006 ("Law 1006") within Senhava, Kuraca has breached the *jus cogens* norm of non-intervention.<sup>59</sup> A State which legislates beyond its extraterritorial competence infringes the sovereignty of the State over which it wrongly asserts jurisdiction.<sup>60</sup> Kuraca has no jurisdiction to regulate the actions of M-S, a Senhavan national. Moreover, its attempt to displace local laws for Kuracan nationals collaborating with foreign persons constitutes foreign State compulsion, and is invalid at international law.<sup>61</sup> State practice demonstrates that a State cannot compel its nationals to impose politically-motivated legislation onto foreign subsidiaries.<sup>62</sup> Law 1006 is an attempt to impose Kuracan ideology upon Senhava, and is an affront to Senhava's political independence.<sup>63</sup> Smith, in forwarding information relevant to Kuracan regulatory procedures, is enforcing Kuraca's legislation within Senhava's territory. Such acts are contrary to international law without the express consent of the encumbered State.<sup>64</sup> It would

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<sup>59</sup> *Declaration on Principles of International Law concerning Friendly Relations and Co-Operation among States in accordance with the Charter of the United Nations*, G.A. Res. 2625, 25 U.N. GAOR Supp. (No. 28) 121, U.N. Doc. A/8028 (1970); *Military and Paramilitary Activities (Merits)*, *supra* n. 35, 147; Damrosch, *Politics Across Borders: Non-Intervention and Non-Forcible Influence over Domestic Affairs*, 83 AM. J. INT'L L. 1, 10-11 (1989).

<sup>60</sup> Akehurst, *Jurisdiction in International Law*, BRIT. Y.B. INT'L L. 145, 179 (1972-3).

<sup>61</sup> THIRD RESTATEMENT, *supra* n. 40, para. 441; LANGE & BORN, EXTRATERRITORIAL APPLICATION OF NATIONAL LAWS 46 (1987).

<sup>62</sup> *Necessity of Ending the Economic, Commercial and Financial Embargo Imposed by the United States of America against Cuba*, G.A. Res. 19, U.N. GAOR, 47th Sess., U.N. Doc. A/ES/47/19; Cuban Liberty and Democratic Solidarity (Libertad) Act 1996 (U.S.) (Helms-Burton Act); *Fruehauf Corp v. Massardy*, 5 I.L.M. 476 (Fr.) (1967).

<sup>63</sup> Akehurst, *supra* n. 60, at 159, 188.

<sup>64</sup> *Panevezys-Saldutiskis Railway*, *supra* n. 49, at 357; Akehurst, *supra* n. 60, at 147.

be improper to construe Senhava's consent to Smith's presence as an express consent to limit its own sovereignty.

#### **IV. KURACA BREACHED CUSTOMARY INTERNATIONAL LAW BY INTERVENING TO HALT THE VACCINE TRIAL**

Kuraca, through its M.P.R.A., has exerted pressure on M-S to halt the Senhavan trials.

This intervention amounts to a breach of the obligation to maintain international peace and security, and the obligation to cooperate in the protection of the right to health and to respect the right to life of all peoples. It also amounts to a breach of the prohibition against cruel, inhuman and degrading treatment.

##### **A. Kuraca breached its obligation to take effective measures for the removal of threats to international peace and security**

The obligation on Members of the U.N. to take effective measures for the prevention and removal of threats to the peace is a codification of customary international law.<sup>65</sup> In acknowledging that the health of all peoples is fundamental to peace and security,<sup>66</sup> international law explicitly recognises the obligation on all States to cooperate in removing threats to the health of all people. The substantive content of this obligation includes the duty to prevent, treat and control pandemics.<sup>67</sup> M.H.V.D. is a deadly disease which already affects

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<sup>65</sup> U.N. CHARTER arts. 1, 103; SIMMA et al., *THE CHARTER OF THE UNITED NATIONS*, 49-56 (1995).

<sup>66</sup> Constitution of the World Health Organization, *opened for signature* July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185, Preamble, para. 3 [hereinafter W.H.O. Const.]; *Legality of the Use by a State of Nuclear Weapons in Armed Conflict*, 1996 I.C.J. 66, 133 (July 8) (diss. op. Judge Weeramantry); *In Address to Security Council, Secretary-General says Fight against AIDS in Africa Immediate Priority in Global Effort against Disease*, U.N. Doc. SG/SM/7275 SC/6780 (Jan. 6, 2000) 2.

<sup>67</sup> W.H.O. Const., *supra* n. 66, Preamble, para. 1; 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) art. 12, para. 2(c) (I.C.E.S.C.R.)

over 20% of Senhava's population. It is extremely contagious, being transmitted by air, water, human bodily fluids and insects. Like the H.I.V. pandemic, which currently affects 33.6 million people worldwide,<sup>68</sup> it disproportionately burdens developing countries, has reached epidemic proportions within the course of a decade, and requires a vaccine for its control.<sup>69</sup> However, M.H.V.D. poses an even greater threat than H.I.V. because it spreads via more vectors, and almost invariably leads to death within three years. The Security Council has recently confirmed that the H.I.V. pandemic presents a real and present danger to world security.<sup>70</sup> In preventing the Senhavan vaccine trials, Kuraca has directly impeded Senhava's endeavours to remove the M.H.V.D. threat to international peace and security.

**B. Kuraca breached its obligation to cooperate in the attainment of the highest standard of health**

The right of every human being to enjoy the highest attainable standard of health has passed "beyond the field of good intentions into the realm of binding international law".<sup>71</sup> Its customary status is evidenced by its presence in foundational international conventions<sup>72</sup> and

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<sup>68</sup> Joint United Nations Programme on HIV/AIDS and World Health Organisation, *AIDS Epidemic Update December 1999* (1999) 3.

<sup>69</sup> *Id.* 4; Pape et al., *The Urge for an AIDS Vaccine: Perspectives from a Developing Country*, 8 AIDS RESEARCH & HUMAN RETROVIRUSES 1535 (1992); KERNS, ETHICAL ISSUES IN HIV VACCINE TRIALS 24-8 (1997).

<sup>70</sup> Vice-President Al Gore, *Opening Statement in the Security Council Meeting on AIDS in Africa, January 10, 2000* (visited Jan. 10, 2000) <[http://www.un.int/usa/00\\_003.htm](http://www.un.int/usa/00_003.htm)>.

<sup>71</sup> *Use of Nuclear Weapons*, *supra* n. 66, 143-4 (diss. op. Judge Weeramantry).

<sup>72</sup> U.N. CHARTER arts. 55, 56; W.H.O. Const., *supra* n. 66; *Universal Declaration of Human Rights*, G.A. Res. 217, U.N. Doc. A/810, at 71 (1948), art. 25, para. 1 (U.D.H.R.); I.C.E.S.C.R. *supra* n. 67, art. 12; International Convention on the Elimination of All Forms of Racial Discrimination, G.A. Res. 2106 A (XX), U.N. GAOR 23d Sess. (1969), 660 U.N.T.S. 195 (entered into force Jan. 4, 1969) art. 5, para. e(iv) (I.C.E.R.D); Convention on the Rights of the Child, G.A. Res. 44/25, annex, 44 U.N. GAOR Supp. (No. 49) at 167, U.N. Doc. A/44/49 (1989) (entered into force Sept. 2, 1990) Annex, Agenda Item 108, at 12-13, art. 24 (C.R.C); European Social Charter, 529 U.N.T.S. 89 (entered into force Feb. 26, 1965)

resolutions,<sup>73</sup> as well as municipal Constitutions.<sup>74</sup> The right to health has also been upheld by international tribunals and domestic courts.<sup>75</sup> Members of this Court have expressly endorsed the obligation of each State to respect this right, not merely to their own subjects, but to all members of the international community.<sup>76</sup> This *erga omnes* status is supported by the absence of any State objection to the specific implementation measures urged on all States.<sup>77</sup> Kuraca's obligation to respect the right of all human beings is therefore not limited to its membership of the W.H.O. and C.R.C., and its obligation not to frustrate the objects

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Part I, art. 11; 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) art. 4; *Human Rights and Scientific and Technological Developments*, G.A. Res. 189, U.N. GAOR, 37<sup>th</sup> Sess., art. 16 (1982).

<sup>73</sup> American Declaration of the Rights and Duties of Man, reprinted in Basic Documents Pertaining to Human Rights in the Inter-American System, OEA/Ser.L.V/II.82 doc.6 rev.1 at 17 (1992) art. 11; Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, "Protocol of San Salvador", O.A.S.T.S. 69 (Nov. 17, 1988), art. 10; Cairo Declaration of Human Rights in Islam, adopted by Organisation of the Islamic Conference (Aug. 1990), art. 17; Declaration on Social Progress and Development, G.A. Res. 2542, U.N. GAOR, 24<sup>th</sup> Sess. (No. 30) at 49, U.N. Doc. A/7630 (1969); World Health Organization, *Global Strategy for Health for All by the Year 2000* (1981), adopted by 34<sup>th</sup> World Health Assembly Res. 34.36.

<sup>74</sup> NETH. CONST. (Oct. 1989) art. 22, para 1; NOR. CONST. (May 17, 1814, amended July 23, 1995) art. 110, para. b; PHIL. CONST. (1987) art. 2, § 15; INDIA CONST. (1949) art. 21; ITALY CONST. (1947) art. 32; S. AFR. CONST. (1996) art. 27; COLOM. CONST. (1991) art. 49.

<sup>75</sup> Case 7615, Inter-Am. C.H.R. Annual Report 1984-1985, Resolution No 12/85, (Brazil), 5 March 1985; President Amsterdam District Court, Aug. 11, 1988 (*Methadon Case*), KG 88, 352 (doc. 3549); *Bandhua Mukti Morcha v. Union of India*, [1984] A.I.R. 802, para. 10 (India); *Minors Oposa v. Secretary of the Department of Environmental and Natural Resources (DENR)*, 33 I.L.M. 173 (1994) (Phil.).

<sup>76</sup> *Use of Nuclear Weapons*, *supra* n. 66, 144 (diss. op. Judge Weeramanty).

<sup>77</sup> Declaration of Alma-Ata on Primary Health Care, adopted at the International Conference on Primary Health Care, Sept. 12, 1978, W.H.O.; *Use of Nuclear Weapons*, *supra* n. 66, 145 (diss. op. Judge Weeramanty).

and purpose of the I.C.E.S.C.R., to which it is signatory.<sup>78</sup>

The obligation to take steps necessary to realize the highest attainable standard of health explicitly requires States to act in preventing, treating and controlling epidemics.<sup>79</sup> Kuraca must also act cooperatively in this obligation.<sup>80</sup> In intervening to halt the world's most advanced M.H.V.D. vaccine trial, Kuraca is breaching its obligation to cooperate in addressing a serious health threat. At the minimum, it is breaching an obligation not to obstruct health programs being implemented in another country.<sup>81</sup> This is because, as urged by the WHO, the vaccine trial is essential for the control of the M.H.V.D. pandemic. The treatment of symptoms alone is irresponsible, without an attempt to eradicate the disease.<sup>82</sup>

### C. Kuraca breached its obligation to protect the right to life

The obligation on all States to respect and ensure the right to life has emerged from the great codified rights<sup>83</sup> to become a peremptory norm of international law.<sup>84</sup> The concept of

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<sup>78</sup> 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. 18 (V.C.L.T.).

<sup>79</sup> I.C.E.S.C.R., *supra* n. 67, art. 12, para. 2(c); European Social Charter, *supra* n. 72, Part II, art. 11, para. 3; Protocol of San Salvador, *supra* n. 73, art. 10, para. 2(d); W.H.O., *Global Strategy*, *supra* n. 73, Part II, para. 1, 31.

<sup>80</sup> I.C.E.S.C.R., *supra* n. 67, art. 2, para. 1; W.H.O. Const., *supra* n. 66, Preamble; C.R.C., *supra* n. 72, art. 24, para. 4; *Use of Nuclear Weapons*, *supra* n. 66, 146 (diss. op. Judge Weeramantry) 218 (diss. op. Judge Koroma).

<sup>81</sup> Jamar, *The International Human Right to Health*, 22 S.U.L. REV. 1, 58-59 (1994).

<sup>82</sup> *Use of Nuclear Weapons*, *supra* n. 66, 135 (diss. op. Judge Weeramantry).

<sup>83</sup> U.D.H.R., *supra* n. 72, art 3; International Covenant on Civil and Political Rights, G.A. Res.2200 (XXI), December 16, 1966, U.N. GAOR, 21<sup>st</sup> 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. 6, para. 1 (I.C.C.P.R.); 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. 2, para. 1 (E.C.H.R.); American Convention on Human Rights, Nov.22, 1969,

arbitrary deprivation of life invokes a general standard, which has been held to apply outside a nation's territory.<sup>85</sup> Categories of arbitrary deprivations have expanded to include the failure to act in the face of circumstances "which could lead to, or are causing deaths on a widespread scale."<sup>86</sup> In holding that the right to life cannot properly be understood in a restrictive manner, the Human Rights Committee has confirmed that it requires States to adopt positive measures, including measures to eliminate epidemics.<sup>87</sup>

**D. Kuraca breached the prohibition against cruel, inhuman and degrading conduct**

The prohibition against cruel, inhuman or degrading treatment is a peremptory norm of international law.<sup>88</sup> Kuraca's obligation to refrain from such treatment therefore exists outside of its clear treaty obligations,<sup>89</sup> and extends beyond Kuraca's own subjects.<sup>90</sup> The

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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. 4, para. 1.

<sup>84</sup> Gormley, *The Right to Life and the Rule of Non-Derogability: Peremptory Norms of Jus Cogens*, in *THE RIGHT TO LIFE IN INTERNATIONAL LAW* 120, 121 (Ramcharan ed., 1985); Parker and Neylon, *Jus Cogens: Compelling the Law of Human Rights*, 12 *HASTINGS INT'L & COMP. L. REV.* 411, 431-2.

<sup>85</sup> Kabaalioglu, *The Obligations to "Respect" and "Ensure" the Right to Life*, in *THE RIGHT TO LIFE IN INTERNATIONAL LAW* 160, 177 (Ramcharan ed., 1985).

<sup>86</sup> Ramcharan, *The Concept and Dimensions of the Right to Life*, in *THE RIGHT TO LIFE IN INTERNATIONAL LAW* 1, 20 (Ramcharan ed., 1985).

<sup>87</sup> U.N. GAOR, Hum. Rts. Comm., 16th Sess., General Comment 6, art. 6, (1982) U.N. Doc. HRI/GEN/1/Rev.1 at 6, paras. 1, 5.

<sup>88</sup> *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); *Siderman de Blake v. Republic of Argentina*, 965 F 2d 699, 714-18 (9<sup>th</sup> Cir, 1992); U.D.H.R., *supra* n. 72, art. 5; I.C.C.P.R., *supra* n. 83, art. 7.

<sup>89</sup> 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); I.C.C.P.R., *supra* n. 83.

European Court of Human Rights has determined that a developed country, which had assumed responsibility for the treatment of an A.I.D.S. sufferer, would be breaching the prohibition on cruel and inhuman treatment by returning him to an under-resourced nation.<sup>91</sup> Inhuman treatment therefore includes the removal of necessary health services, once a country has assumed responsibility for providing them.<sup>92</sup> Kuraca has assumed responsibility for alleviating the M.H.V.D. pandemic by allowing M.C. to support a Phase I vaccine trial. It has also assumed responsibility for the immediate prophylactic or curative effects for trial participants, and for the health care which complements participation in a pharmaceutical trial.<sup>93</sup> Kuraca cannot now intervene to remove this health program.

**E. Kuraca cannot justify its actions on the grounds of a need for informed consent**

Kuraca's treaty and customary obligations prohibit it from derogating from its obligations to respect the right to life and refrain from cruel, inhuman or degrading treatment.<sup>94</sup> Kuraca is therefore unable to justify its conduct on the grounds of a need for informed consent, which is unlikely to be admitted as custom and even less likely to be accorded the status of a peremptory norm.<sup>95</sup> Nevertheless, if the Court accepts that a right to informed consent is a valid justification for Kuraca's breach of the right to health, Kuraca's

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<sup>90</sup> ROZAKIS, *THE CONCEPT OF JUS COGENS IN THE LAW OF TREATIES* (1976); Sohn, *The New International Law: Protection of the Rights of Individuals rather than States*, 32 AM. U. L. REV. 1, 32 (1982).

<sup>91</sup> *D. v. United Kingdom*, App. No. 30240/96, 24 Eur. H.R. Rep. 423 (1997) (Eur. Ct. H. R.).

<sup>92</sup> *Id.* para. 53.

<sup>93</sup> LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH*, 2-8 (1981); Alta Charo, *Protecting Us to Death: Women, Pregnancy, and Clinical Research Trials*, 38 ST. LOUIS U.L.J 135, 152 (1993).

<sup>94</sup> I.C.C.P.R., *supra* n. 83, arts. 4, 6, 7; *Compromis*, para. 3.

<sup>95</sup> See *infra* Pleadings, at 18-19.

drastic actions in halting the trial go beyond “the extent strictly required by the exigencies of the situation”<sup>96</sup> and are disproportionate.

## V. THE TRIAL AS PROPOSED IS CONSISTENT WITH SENHAVA’S HUMAN RIGHTS OBLIGATIONS

### A. Senhava has no obligation to obtain informed consent

Senhava’s signature of the Convention on Human Rights and Biomedicine does not entail a positive obligation to obtain informed consent.<sup>97</sup> The only possible source for this obligation is custom, and informed consent is not supported by sufficient State practice and *opinio juris* to constitute a customary norm.<sup>98</sup> Its mere articulation in the Convention - to which reservations may be deposited and derogation permitted<sup>99</sup> - cannot produce custom. International and national guidelines promulgated in this area are predominantly ethical only.<sup>100</sup> State practice has diverged both in recognising the existence of informed consent and its substantive content.<sup>101</sup> If recognised, it has been accorded a different meaning

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<sup>96</sup> I.C.C.P.R., *supra* n. 83, art. 4, para. 1; E.C.H.R., *supra* n. 83, art. 15, para. 1.

<sup>97</sup> Convention on Human Rights and Biomedicine (entered into force Dec.1, 1999) E.T.S. No. 164 (C.H.R.B); V.C.L.T., *supra* n. 78, art. 18.

<sup>98</sup> North Sea Continental Shelf (F.R.G. v. Den., F.R.G. v. Neth.), 1969 I.C.J. 3 (Feb. 20).

<sup>99</sup> C.H.R.B., *supra* n. 97, arts. 5, 26, 36.

<sup>100</sup> Declaration of Helsinki, World Medical Association 18<sup>th</sup> 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].

<sup>101</sup> Miller, *The Informed-Consent Policy of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use*, 30 CORNELL INT’L L.J. 203, 206-27 (1997); Aarons, *Research Ethics*, 44 W. INDIAN MED. J. 115.

depending on the cultural parameters of that State.<sup>102</sup> Kuraca's criteria for informed consent are predicated on Western notions of individual autonomy<sup>103</sup> and require economic and social conditions of industrialised countries for their implementation.<sup>104</sup> It is an obligation that for many countries is culturally obtuse or financially untenable. Furthermore, the technical and complex nature of informed consent prevents it being included with long-standing human rights norms.<sup>105</sup>

**B. Alternatively, Senhava has fulfilled any requirements to obtain informed consent**

If the Court identifies a customary obligation of informed consent, it must include a margin for cultural and economic variation.<sup>106</sup> Senhava is therefore permitted to mandate its own professional ethical standard, as based on the enduring principles of the Hippocratic Oath. This Oath ensures the utmost respect for human life without discrimination, and governs medical practice in both developing and developed countries.<sup>107</sup> The proposed trial required voluntary participants to give consent through signature, after acknowledging the risk of ill effects. A special procedure was designed for illiterate or foreign-language subjects, and children.<sup>108</sup> Senhava therefore fulfilled any obligation to obtain informed

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<sup>102</sup> Leflar, *Informed Consent and Patients' Rights in Japan*, 33 HOUS. L. REV. 1 (1996); Tsukamoto, *Patient's Autonomy vs Doctor's Professionalism*, 15 MED. & L. 195 (1996).

<sup>103</sup> LEVINE, *supra* n. 93, 8-10.

<sup>104</sup> Varmus & Satcher, *Ethical Complexities of Conducting Research in Developing Countries*, 337 NEW ENG. J. MED. 1003, 1003-4 (1997).

<sup>105</sup> *North Sea Continental Shelf*, *supra* n. 98.

<sup>106</sup> C.I.O.M.S. GUIDELINES, *supra* n. 100, Guideline 8.

<sup>107</sup> World Medical Association in Geneva, *The Declaration of Geneva, 1948: A 1971 Reappraisal*, 2 MED. J. AUSTL. 735, (1971); Integrated Healthcare Association (U.S.), *Does Managed Care Require a "New" Medical Ethics?* ETHICAL ISSUES MANAGED CARE QUARTERLY (1998).

<sup>108</sup> *Compromis*, para. 20.

consent.

**C. Senhava has not breached obligations of non-discrimination**

Senhava's Hippocratic Oath, and the proposed trial, are consistent with its treaty<sup>109</sup> and customary obligations of non-discrimination.<sup>110</sup> Whilst international law recognises a principle of equality of treatment, differential treatment, if reasonable and proportionate to the purpose of the action, does not constitute discrimination.<sup>111</sup> The test subjects reflect a cross-section of the community.<sup>112</sup> The use of high- rather than low-risk participants is essential to measure the efficacy of the vaccine, as it derives more conclusive results.<sup>113</sup> It would be scientifically unsound for Senhava to exclude entire groups, such as women and children, from clinical trials for drugs intended for their use.<sup>114</sup>

**VI. SENHAVA INCURRED NO LIABILITY REGARDING MEGACEUTICAL-SENHAVA**

If M-S is a Kuracan national, which Senhava denies, Senhava may take measures contrary to its Treaty of Amity and Commerce without incurring international responsibility. Measures taken against M-S are justified by a 'state of necessity' under customary

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<sup>109</sup> Convention on the Elimination of All Forms of Discrimination Against Women, G.A. Res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46, (entered into force Sept. 3, 1981); C.R.C., *supra* n. 72.

<sup>110</sup> The Declaration of Geneva, 1948, *supra* n. 107.

<sup>111</sup> Laws on the Use of Languages in Education in Belgium, App. No. 1474/62, 1 Eur. H.R. Rep. 252 (1968) (Eur. Ct. H. R.); De Geillustreerde Pers N.V. v. Netherlands, App. No. 5178/77, 8 Eur. Comm'n. H.R. Dec. & Rep. 5 (1977).

<sup>112</sup> *Compromis*, para. 15.

<sup>113</sup> Lurie et al., *Ethical, Behavioral, and Social Aspects of HIV Vaccine Trials in Developing Countries*, 271 JAMA 295, 296 (1994).

<sup>114</sup> Merton, *The Exclusion of Pregnant, Pregnable, and Once-pregnable people (a.k.a Women) from Biomedical Research*, 3 TEX. J. OF WOMEN & LAW 307 (1994); Alta Charo, *supra* n. 93, 135.

international law.<sup>115</sup> In the face of an imminent threat or danger, a government may take extraordinary measures to safeguard its essential interests without incurring international responsibility.<sup>116</sup> A State has an essential interest in the survival of its population.<sup>117</sup> A threat may be imminent even though its effects are not immediate, so long as they are no less certain or inevitable.<sup>118</sup> M.H.V.D., without a cure, will lead to the deaths of over 20% of Senhava's population. The measures taken by Senhava were necessary to protect its population, in light of Kuraca's obstruction of the trial.

## VII. SENHAVA'S DETENTION OF GEORGE SMITH DOES NOT VIOLATE INTERNATIONAL LAW

Only the basic prohibition against arbitrary detention forms part of customary international law.<sup>119</sup> The elaborate procedural stipulations of Article 9 of the ICCPR are not binding on Senhava, as it is not a party.<sup>120</sup>

The *travaux-preparatoires* of the ICCPR provisions concerning arbitrary detention demonstrate that negotiating parties considered it uncontroversial that the prohibition was derogable in times of public emergency.<sup>121</sup> Public emergencies which threaten the very life

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<sup>115</sup> *Gabcikovo-Nagymaros Project (Hung. v. Slov.)*, 1997 I.C.J. 7, para. 51 (Sep. 25).

<sup>116</sup> *Report of the Commission to the General Assembly on the Work of its 32d. Session*, [1980] 2 Y.B. Int'l L Comm'n. A/CN.4/SER.A/1980/Add.1 (Part 2) art 33; *Gabcikovo-Nagymaros Project*, *supra* n. 115, para. 52; *Sea-Land Services Inc. v. Iran*, 6 Iran-U.S. C.T.R., 149, 165 (June 20, 1984).

<sup>117</sup> *Report of the Commission to the General Assembly on the Work of its 32d. Session*, [1980] 2 Y.B. Int'l L Comm'n. 35, para. 3, A/CN.4/SER.A/1980/Add.1 (Part 2).

<sup>118</sup> *Gabcikovo-Nagymaros Project*, *supra* n. 115, para. 54.

<sup>119</sup> Lillich, *Civil Rights*, in *HUMAN RIGHTS IN INTERNATIONAL LAW : LEGAL AND POLICY ISSUES* 115, 139 (Meron ed., 1985).

<sup>120</sup> *Compromis*, para. 3.

<sup>121</sup> BOSSUYT, *GUIDE TO THE "TRAVAUX PREPARATOIRES" OF THE INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS* 87 (1987).

of the nation routinely require special measures, including preventive detention, to protect the security of the nation.<sup>122</sup>

The M.H.V.D. pandemic afflicting Senhava amounts to a public health emergency which threatens the life of the nation and its entire population. Accordingly, the Senhavan Ministry of Health has declared a state of emergency. Smith's conduct threatened the capacity of the Senhavan state to take the measures necessary to control the M.H.V.D. pandemic, and as such, was a threat to the security of the State and its population. He has been detained to prevent him from further jeopardizing Senhava's efforts to protect its security and its population. He will also face criminal charges. Under the circumstances of the M.H.V.D. pandemic, detention for four months without charge or judicial review is not unreasonable nor capricious.

Thus, Smith's detention is, firstly, a question of national security, and, secondly, a criminal matter wholly within the sovereignty of Senhava. It is well recognized in international law that an alien is subject to all the penal laws of the State in which he or she is located. Detention of an alien does not breach international law if there is probable cause for arrest, and if the proceedings are in accordance with the laws of that State.<sup>123</sup>

## **VIII. REMEDIES**

### **A. Kuraca must repeal or alter Kuracan National Health Law 1006**

As an impermissible exercise of extraterritorial jurisdiction, Law 1006 violates international law. The international law concept of restitution includes legal restitution, whereby the wrongdoing State corrects the measure of its legislature that infringes

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<sup>122</sup> UNITED NATIONS COMMISSION ON HUMAN RIGHTS, STUDY OF THE RIGHT OF EVERYONE TO BE FREE FROM ARBITRARY ARREST, DETENTION AND EXILE 184 (1964).

<sup>123</sup> Roberts Case (U.S. v. Mex.), 4 R.L.A.A. 77 (Gen. Cl. Comm'n. 1926); FREEMAN, THE INTERNATIONAL RESPONSIBILITY OF STATES FOR DENIAL OF JUSTICE 209 (1938).

international law.<sup>124</sup> In order to terminate the illegal conduct and ‘wipe out’ the consequences of the breach, Kuraca must repeal or alter National Health Law 1006 to the extent it that impedes the conduct of M.H.V.D. vaccine trials in Senhava as proposed in the research protocol. This Court has the power to make a mandatory order to this effect.<sup>125</sup>

**B. Kuraca must pay compensatory damages to Senhava for the cost of treating victims of M.H.V.D.**

Kuraca’s breach of its international obligations to Senhava entitle Senhava to compensatory damages to the value of the loss caused by the breach. Kuraca must pay damages of a value which wipe out the consequences of the illegal act and reestablish the situation that would have existed had the breach not occurred.<sup>126</sup>

Compensable damage includes loss which is a proximate result or consequence of the injurious act.<sup>127</sup> Loss for which a wrongdoer is liable is loss caused by his breach and which is reasonably foreseeable at the time of the wrong.<sup>128</sup> Compensation should not be denied merely because the loss is imprecise or difficult to calculate.<sup>129</sup>

A reasonably foreseeable consequence of Kuraca’s illegal obstruction of M.H.V.D. vaccine trials in Senhava is the continuing rapid increase in M.H.V.D. infections, and

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<sup>124</sup> GARCIA-AMADOR, SOHN & BAXTER, RECENT CODIFICATION OF THE LAW OF STATE RESPONSIBILITY FOR INJURY TO ALIENS 100 (1974).

<sup>125</sup> Mann, *The Consequences of An International Wrong in International and Municipal Law* 48 BRIT. Y. B. INT’L L. 1, 13 (1976-7); United States Diplomatic and Consular Staff in Tehran (U.S. v. Iran) 1980 I.C.J. 2, 44-5 (May 24).

<sup>126</sup> Chorzów Factory Case (Merits) (Ger. v. Pol.), 1928 P.C.I.J. (ser. A) No. 17, 47 (Sep. 13).

<sup>127</sup> Administrative Decision No. II (U.S. v. Ger.), 7 R.I.A.A. 23, 29 (Gen. Cl. Comm’n. 1923).

<sup>128</sup> Samoan Claims (Ger. v. Gt. Brit./U. S.), 9 R.I.A.A. 15 (Spec. Arb. 1902).

<sup>129</sup> Company General of the Orinoco Case (Fr. v. Venez.), 10 R.I.A.A. 184 (Mix. Cl. Comm’n. 1903).

associated public health costs. Given that Phase I vaccine trials demonstrated a “substantial improvement”<sup>130</sup> in 93 percent of patients treated, alleviation of the disease across a large section of the population was a probable consequence of conducting large-scale trials. Foregone health benefits to the Senhavan population are thus a real and foreseeable consequence of Kuraca’s illegal obstruction of the trial. Kuraca must compensate Senhava for this loss, which is neither contingent nor indeterminate.

**C. Senhava is not liable to refund Euros 2 million paid by Megaceutical Corporation**

It is disingenuous of Kuraca to claim that M.C. is entitled to a return of the advance payment for the conduct of the trial. Kuraca has deliberately obstructed the conduct of the trial in violation of international law, and is therefore responsible for the conditions frustrating M.C.’s completion of the trial.

**D. The Court does not have jurisdiction to order the release of George Smith**

This Court does not function as a court of criminal appeal, and cannot make orders in the nature of a *habeas corpus*.<sup>131</sup> As Smith is detained pursuant to Senhavan criminal legal processes, an order for his release amounts to an unwarranted interference with the sovereign criminal jurisdiction of Senhava. There is no rule of international law requiring the Court to order his release if it would exceed the practice and jurisdiction of the Court.<sup>132</sup>

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<sup>130</sup> *Compromis*, para 13.

<sup>131</sup> Vienna Convention on Consular Relations (Para. v. U. S.), 1998 I.C.J. 266 (Apr. 9). (decl. Judge Oda), (decl. Judge Koroma).

<sup>132</sup> *Savarkar* (Gr. Brit. v. Fr.), 11 R.I.A.A. 243 (Perm. Ct. Arb. 1911).

## **IX. PRAYER FOR RELIEF**

The Republic of Senhava respectfully requests this Honorable Court to:

- 1) decline jurisdiction;
- 2) declare that Kuraca violated the duty to maintain peace and security and the duty of non-intervention;
- 3) declare that Kuraca has violated the Senhavan population's right to health and right to life and is responsible for acts of cruel, inhuman and degrading treatment;
- 4) order that Kuraca alter or repeal National Health Law 1006 to the extent that it violates international law, and remove all legal and governmental obstacles to the conduct of M.H.V.D. trials in Senhava;
- 5) award monetary damages to compensate Senhava for public health expenses reasonably incurred because of Kuraca's illegal obstruction of the M.H.V.D. vaccine trials.

Respectfully submitted on this day,

Friday January 21, 2000

**THE REPUBLIC OF SENHAVA**

