

**The 2000 Philip C. Jessup  
International Law Moot Court Competition**

**State of Kuraca**

**v.**

**Republic of Senhava**

*The Case Concerning the Vaccine Trials*

**BEST OVERALL MEMORIAL - APPLICANT**

**First Place  
Richard R. Baxter Award**

**Univeristy of Alabama  
United States (Team #509)**



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

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**Case Concerning the Vaccine Trials  
in the Republic of Senhava**

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The State of Kuraca,  
Applicant

v.

The Republic of Senhava,  
Respondent

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Spring Term 2000

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On Submission to  
the International Court of Justice

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**Memorial for the Applicant**

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## STATEMENT OF JURISDICTION

The State of Kuraca and the Republic of Senhava have submitted their differences concerning the vaccine trials to the International Court of Justice for resolution through a Special Agreement, in accordance with Article 40(1) of the Statute of the International Court of Justice. Both States have accepted the jurisdiction of this Court pursuant to Article 36(2) of the Statute. The Convention Against Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment and the Convention on the Elimination of All Forms of Discrimination Against Women also confer jurisdiction on this Court pursuant to Article 36(1) of the Statute of the International Court of Justice.

## STATEMENT OF THE FACTS

The State of Kuraca is a large, industrialized country with a developed economy and an extensive higher education system. It is also a world leader in biotechnology. The Republic of Senhava is a small, developing country containing diverse ethnic and language groups, several of which live in total isolation. Kuraca and Senhava have always maintained normal trading relations with each other. However, their current relations are strained due to their disagreement over the Multivector Hepatic Viral Disease (“MHVD”) vaccine trials.

MHVD is a deadly and contagious disease that attacks the human liver, disrupts the digestive system, and ultimately leads to death within three years. MHVD can be transmitted through air, water, human bodily fluid, and several kinds of flies and mosquitoes. MHVD was unknown to public health authorities until 1988, and in 1996, the World Health Organization (“WHO”) declared MHVD a worldwide pandemic. A WHO Special Panel on MHVD found that clean water, sanitation, pest control, and avoiding unsafe sexual practices are the only reliable defenses against the disease, but it urged that a vaccine be developed to combat the disease.

Because a vaccine to prevent this deadly and pervasive disease is in demand, Megaceutical Corp. (“Megaceutical”), a multinational pharmaceutical company incorporated in Kuraca, began developing a potential MHVD vaccine. Megaceutical conducted research to find a vaccine, and it later conducted small-scale tests of various vaccine formulas in Senhava through its subsidiary, Megaceutical-Senhava, Ltd. (“M-S”). Though Megaceutical is not permitted to own more than forty-nine percent of M-S under Senhavan law, Megaceutical retains control over M-S through a shareholder agreement.

In the Phase I (toxicity) vaccine trial conducted by M-S, two of the thirty Senhavan test subjects developed a debilitating form of asthma. However, Megaceutical decided to continue

the vaccine trials in large populations using a variation of the original vaccine, Vaccine 078c. M-S procured Senhava's permission to continue the vaccine trials, at the corporation's expense, in return for payment of an equivalent of Euros 2,000,000 to the Senhavan Health Ministry. In return, the Senhavan Health Ministry allowed the trials to target orphanages, prisons, maternal and child health clinics, and people in outer island villages. Also, the Senhavan National Police were to transport M-S personnel supervising the trials.

Megaceutical hired Dr. Maria Yukawa-Lopez to oversee the vaccine project. Dr. Yukawa-Lopez submitted the Biomedical Research Protocol ("Protocol" or "Research Protocol") to the Kuraca Capital University Biomedical Ethics Review Board ("Board") for its approval. Though the Protocol included an "informed consent" form ("Consent Form"), the Board concluded that the Senhavan test subjects were not adequately protected due to the vulnerability of the proposed study populations, the small likelihood that any voluntary consent would actually be fully informed, the use of placebos in areas where the disease is active, and the absence of a credible biomedical ethics review board in Senhava. The Board also warned that Kuracan Capital University physicians and faculty working on these proposed vaccine trials would risk losing their medical licenses if they proceeded to implement the Protocol.

The Kuracan Medical Product Regulation Agency ("Agency") hired George Smith, a citizen of Nemin, to provide on-site reporting and advisory services to M-S. Senhava agreed to permit George Smith to perform these services. Smith sent copies of the Research Protocol and Consent Form to the Agency, along with his recommendation that the vaccine trials be canceled. After reviewing Smith's recommendation, documents, and the Board's opinion, the Agency warned Megaceutical to halt the vaccine trials on "humanitarian" grounds, according to an industry newsletter.

Citing these developments, Dr. Yukawa-Lopez resigned from the vaccine project. As a result of her resignation and the Agency's warning, Megaceutical terminated the project. Subsequently, Senhavan National Police arrested George Smith for giving the Kuracan Medical Product Regulation Agency the documents relating to the drug trials. Smith continues to be held without bail, without being formally charged, and without a trial date scheduled. Kuraca has demanded Smith be freed. On September 16, 1999, Senhava's Ministry of Health declared a MHVD public health emergency and ordered M-S to continue the vaccine trials or face substantial fines and imprisonment of its officers. On September 22, after refusing to comply with Senhava's orders to continue the vaccine trials, Senhava closed M-S's offices and continues to levy a fine of \$100,000 per day.

Kuraca maintains that it has jurisdiction to regulate its corporations and comply with its obligations under international law regarding human rights, while Senhava maintains that this is a Senhavan domestic health issue and thus outside of Kuraca's prescriptive jurisdiction. Diplomatic intervention has failed to resolve this impasse. Kuraca now petitions this Court to resolve the dispute. Though Senhava objects to this Court's jurisdiction, both parties have agreed to a jointly-prepared Compromis to expedite proceedings.

## QUESTIONS PRESENTED

- I. WHETHER THE INTERNATIONAL COURT OF JUSTICE HAS JURISDICTION OVER THIS DISPUTE.
- II. WHETHER KURACA HAS JURISDICTION UNDER INTERNATIONAL LAW TO APPLY KURACAN NATIONAL HEALTH LAW 1006 TO MEGACEUTICAL-SENHAVA.
- III. WHETHER KURACA'S LAWS AND REGULATIONS PROTECTING THE HUMAN RIGHTS OF PEOPLE INVOLVED IN MEDICAL EXPERIMENTATION COMPLY WITH ITS OBLIGATIONS UNDER INTERNATIONAL LAW.
- IV. WHETHER SENHAVA IMPROPERLY IMPRISONED GEORGE SMITH FOR PERFORMING HIS DUTIES FOR THE KURACAN MEDICAL PRODUCT REGULATION AGENCY.
- V. WHETHER SENHAVA SHOULD PAY COMPENSATION FOR INJURIES CAUSED BY ITS BREACHES OF INTERNATIONAL LAW.

## SUMMARY OF THE PLEADINGS

**I.** This Court has jurisdiction over this dispute based on three separate grounds: 1) the Compromis, 2) Kuraca and Senhava's declarations accepting this Court's jurisdiction, and 3) pre-existing treaties that confer jurisdiction on this Court. The dispute is international in scope because human rights would be violated if the Research Protocol were implemented, and MVHD is a worldwide pandemic. Thus, Senhava is divested of any claim that this is a domestic issue. Further, Nemin is not a necessary party to this dispute, as its rights will not form the subject-matter of this Court's judgment. In addition, the multilateral treaty reservation is inapplicable because this case involves treaties that codify existing customary international law.

**II.** Kuraca has jurisdiction under international law to apply the Kuracan National Health Law to M-S for five reasons. First, Kuraca has jurisdiction under the subjective territoriality principle because Megaceutical planned the vaccine trials. Second, Kuraca has jurisdiction under the universality principle to protect the human rights of the Research Protocol test subjects. Third, Kuraca has jurisdiction under the nationality principle because Megaceutical is a national of Kuraca. Fourth, the extraterritorial application of the Kuracan National Health Law is reasonable, in that a Kuracan corporation controls the vaccine trials, and the human rights that would be violated in these vaccine trials are of international concern. Fifth, the Vienna Convention on the Law of Treaties allows Kuraca to suspend the Treaty of Amity and Commerce and thus apply its health law to Senhava because Senhava breached the treaty first by closing M-S's offices, threatening its officers, and fining the company.

**III.** International law prohibits the Research Protocol for three reasons. First, human rights treaties to which both Senhava and Kuraca are parties prohibit the Research Protocol because it endangers and exploits vulnerable Senhavans without their free and informed consent, thereby

undermining the treaties' guarantees of human dignity and integrity. Second, the Research Protocol specifically violates the Convention on Human Rights and Biomedicine ("CHRB") because it does not ensure the free and informed consent of the targeted populations and because it does not provide for a Senhavan ethics review board. Third, the Research Protocol violates customary international law and customary international human rights law because it subjects the targeted Senhavans to medical experimentation without their free and informed consent, and it does not require an ethics review board.

IV. Kuraca has authority to object to the unlawful imprisonment of George Smith, a citizen of the Republic of Nemin, pursuant to Kuraca's interest in Smith as its agent. Senhava violates Articles 9 and 10 of the Universal Declaration of Human Rights by arbitrarily arresting Smith and holding him without bail, without presenting formal charges, and without setting a trial date.

V. Customary international law dictates that Senhava should pay compensation for all damages resulting from its breaches of the Treaty of Amity and Commerce, the Convention on the Elimination of All Forms of Discrimination Against Women, the Convention Against Torture Other Cruel, Inhuman, or Degrading Treatment or Punishment, and the Convention on the Rights of the Child. Further, Senhava should return the payment of Euros 2,000,000 previously advanced by Megaceutical, pay for all damages resulting from the closing of M-S, and cease all conduct from which the breaches arise.



## PLEADINGS AND AUTHORITIES

### **I. THE INTERNATIONAL COURT OF JUSTICE HAS JURISDICTION OVER THIS DISPUTE.**

This Court has jurisdiction based on the declarations of Kuraca and Senhava accepting this Court's compulsory jurisdiction,<sup>1</sup> the Compromis,<sup>2</sup> and treaties which directly confer jurisdiction on this Court.<sup>3</sup> Senhava asserts that this Court lacks jurisdiction because: 1) The dispute exclusively concerns matters which are essentially within the domestic jurisdiction of Senhava, as determined by Senhava; and 2) the Republic of Nemin is not a party to the case. However, norms of international law do not support Senhava's objections to this Court's jurisdiction, regardless of which basis for jurisdiction the objections are applied.

#### **A. Senhava's domestic jurisdiction objection does not divest this Court of jurisdiction.**

In an apparent attempt to reciprocally assert Kuraca's domestic jurisdiction reservation, Senhava urges that the issues in this case "are purely internal to Senhava"<sup>4</sup> and attempts to take advantage of the subjective clause of Kuraca's reservation.<sup>5</sup> However, whether Senhava asserts

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<sup>1</sup> See Statute of the International Court of Justice, June 26, 1945, art. 36, para. 2, 59 Stat. 1055, T.S. 993 [hereinafter I.C.J. Statute].

<sup>2</sup> See I.C.J. Statute, *supra* note 1, art. 36, para. 1. See also J. G. Merrills, *The Optional Clause Revisited*, 64 BRIT. Y.B. INT'L L. 197, 198 (1993); SHABTAI ROSENNE, *THE LAW AND PRACTICE OF THE INTERNATIONAL COURT* 333, 370 (2d ed. 1985); RENATA SZAFARZ, *THE COMPULSORY JURISDICTION OF THE INTERNATIONAL COURT OF JUSTICE* 6-7 (1993).

<sup>3</sup> See I.C.J. Statute, *supra* note 1, art. 36, para. 1. See, e.g., Convention Against Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment, *opened for signature* Dec. 10, 1984, art. 30, para. 1, 1465 U.N.T.S. 85, 121 [hereinafter CAT]; Convention on the Elimination of All Forms of Discrimination Against Women, *opened for signature* Dec. 18, 1979, art. 29, 1249 U.N.T.S. 13, 34 [hereinafter CEDAW]; see also discussion *infra* Part III.B.1.

<sup>4</sup> Comp. Issues/Claims p. 13.

<sup>5</sup> See Comp. ¶ 34.

its domestic jurisdiction objection through the doctrine of reciprocity or through its own “reservations” to the Compromis, the objection is not supported by international law.

1. The dispute is international in scope.

The scope of the disagreement between Kuraca and Senhava is essentially international for two reasons: 1) The facts underlying this dispute are international in character; and 2) even if the dispute is domestic, Senhava’s participation in multilateral treaties has elevated the dispute to an international realm. First, the facts have international implications. Because the WHO declared MHVD a worldwide pandemic,<sup>6</sup> concerns about the disease transcend the borders of Senhava. The ease of MHVD’s transmission<sup>7</sup> demonstrates that the pandemic is not localized to Senhava and that it requires an international response. Moreover, this dispute ultimately turns on the international law of human rights. As questions of human rights in the medical experimentation context hold a significant position in international law,<sup>8</sup> this case is properly characterized as essentially international in nature.

Second, to the extent that Megaceutical’s vaccine trials may be domestic in nature, Senhava has elevated that domestic subject matter to an international level by its assent to treaties implicated by the trials. The “theory of relativity” accords international status to issues otherwise domestic when a country enters into an international agreement concerning those same issues.<sup>9</sup> Because this Court must interpret treaties to which Senhava is a party or has signed,<sup>10</sup>

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<sup>6</sup> See *id.* ¶ 6.

<sup>7</sup> See *id.* ¶ 5.

<sup>8</sup> See generally Francesco Francioni, *An International Bill of Rights: Why it Matters, How it Can Be Used*, 32 TEX. INT’L L.J. 471, 481 (1997); see also discussion *infra* Part III.A.

<sup>9</sup> See *Certain Norwegian Loans (Fr. v. Nor.)*, 1957 I.C.J. 9, 23-25; *Interhandel (Switz. v. U.S.)*, 1950 I.C.J. 6, 24 (Mar. 21); *Interpretation of Peace Treaties with Bulgaria, Hungary, and*

the dispute is plainly international.

2. Senhava should not be permitted to subjectively determine whether this dispute is essentially domestic in nature.

Senhava should not be permitted to determine this Court's jurisdiction because: 1) the subjective clause is invalid; and 2) Senhava waived its ability to rely on the subjective clause.

- a. *The subjective clause is invalid.*

Senhava should not be able to assert the subjective clause, reciprocally or through its own reservation contained in the Compromis, because it is invalid. According to the Vienna Convention on the Law of Treaties ("Vienna Convention"), the subjective clause is prohibited by the Statute of the International Court of Justice ("Statute") and therefore is void. The Statute requires that "in the event of a dispute as to whether the Court has jurisdiction, the matter *shall* be settled by a decision of the Court."<sup>11</sup> The United Nations Charter and the Statute support the above mandate by declaring that this Court "shall function in accordance with the . . . Statute."<sup>12</sup> Accordingly, the reservation is void under the Vienna Convention, which clearly states that a state may formulate a reservation "unless the reservation is prohibited by the treaty."<sup>13</sup> Furthermore, since the Vienna Convention codified customary international law regarding

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Romania, 1950 I.C.J. 65, 70-71 (Mar. 30); Advisory Opinion No. 4, Nationality Decrees Issued in Tunis and Morocco (French Zone) on November 8, 1921, 1923 P.C.I.J. (ser. B) No. 4, at 24.

<sup>10</sup> See *infra* Part III.B.1.

<sup>11</sup> I.C.J. Statute, *supra* note 1, art. 36, para. 6 (emphasis added).

<sup>12</sup> U.N. CHARTER art. 92; I.C.J. Statute, *supra* note 1, art. 1.

<sup>13</sup> Vienna Convention on the Law of Treaties, *opened for signature* May 23, 1969, art. 19, 1155 U.N.T.S. 331, 336-37 [hereinafter Vienna Convention]. See also *Certain Norwegian Loans* 1957 I.C.J. at 43-49 (separate opinion of Judge Lauterpacht); SZAFARZ, *supra* note 2, at 54.

reservations,<sup>14</sup> the clause is also invalid under customary international law.

The invalidity of the subjective clause of Kuraca's reservation does not invalidate Kuraca's entire declaration. The Vienna Convention permits an invalid clause to be separated from a treaty where: 1) The separation does not interfere with the application of the remainder of the treaty; 2) the voided clause was not an essential basis for the acceptance of the other parties to the treaty; and 3) the continued performance of the treaty would not be unjust.<sup>15</sup> The elements are easily satisfied: 1) The declaration will function as if the invalid clause never existed; 2) as other states chose not to make the same reservation to their declarations, it may be inferred that no state would have based its acceptance on Kuraca's subjective clause; and 3) the continued utilization of the optional clause is not unjust, as the result is equally binding on all parties that have submitted declarations. However, even if Kuraca's declaration were deemed invalid, the *Compromis*<sup>16</sup> and the treaties<sup>17</sup> provide a second and a third basis for jurisdiction.

b. *Senhava waived the ability to assert the subjective clause.*

The *Compromis* acknowledges this Court's ability to determine its own jurisdiction in three instances.<sup>18</sup> In agreeing to submit this dispute to this Court, Kuraca detrimentally relied on the Senhavan assertions that this Court had the ability to determine its own jurisdiction to the extent that Kuraca by-passed alternative methods of dispute resolution, such as the arbitration

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<sup>14</sup> See James Crawford, *The Legal Effect of Automatic Reservations to the Jurisdiction of the International Court*, 50 BRIT. Y.B. INT'L L. 63, 79 (1981).

<sup>15</sup> Vienna Convention, *supra* note 13, art. 44, para. 3, 1155 U.N.T.S. at 343.

<sup>16</sup> See *supra* note 2.

<sup>17</sup> See *supra* note 3.

<sup>18</sup> See *Comp.* preamble & art. 1.

provisions mandated by treaties implicated in this dispute.<sup>19</sup> Accordingly, Senhava should be estopped from denying this Court the ability to determine its own jurisdiction.<sup>20</sup>

3. If Senhava is permitted to determine the character of this dispute, then the duty of good faith prevents Senhava from characterizing this dispute as essentially domestic.

The Vienna Convention<sup>21</sup> and general principles of international law<sup>22</sup> require treaties to be performed in good faith. Indeed, this Court explained that “[i]n the establishment of this [network of reservations] which constitutes the Optional-Clause system, the principle of good faith plays an important role.”<sup>23</sup> The decidedly international character of this dispute and the theory of relativity<sup>24</sup> preclude a good faith characterization of this dispute as essentially domestic.

**B. Nemin’s absence does not divest this Court of jurisdiction.**

Senhava’s argument that this Court lacks jurisdiction due to Nemin’s absence implicates two issues of international law: 1) the application of the necessary party doctrine and 2) the application of the multilateral treaty reservation, either reciprocally through Kuraca’s declaration or through the Compromis. Neither implication divests this Court of jurisdiction.

1. The necessary party doctrine is not applicable in this case.

The necessary party doctrine applies in cases where an absent state’s rights would

<sup>19</sup> See CAT, *supra* note 3, art. 3, para. 1, 1465 U.N.T.S. at 121; CEDAW, *supra* note 3, art. 29, para. 1, 1249 U.N.T.S. at 34.

<sup>20</sup> See The Territorial Dispute (Libya/Chad), 1994 I.C.J. 6 (Feb. 3) (separate opinion of Judge Ajibola).

<sup>21</sup> Vienna Convention, *supra* note 13, art. 26, 1155 U.N.T.S. at 339.

<sup>22</sup> See J.F. O’CONNOR, GOOD FAITH IN INTERNATIONAL LAW 98 (1991).

<sup>23</sup> Military and Paramilitary Activities in and Against Nicaragua (Nicar. v. U.S.), 1984 I.C.J. 392, 418 (Nov. 26).

<sup>24</sup> See discussion *supra* Part I.A.1.

“constitute the very subject matter of” this Court’s judgment.<sup>25</sup> In other words, the doctrine applies when the absent state’s rights form the “basis” for the judgment, and not simply where the Court’s judgment “might well have implications” for the absent state’s rights.<sup>26</sup>

Nemin has two peripheral connections to this dispute: 1) its national, George Smith, has been unlawfully imprisoned by Senhava;<sup>27</sup> and 2) Nemin is a party to several multilateral treaties to be interpreted by this Court.<sup>28</sup> These insubstantial connections cannot form the basis for this Court’s judgment. First, Nemin’s rights vis-à-vis George Smith will remain unchanged since his nationality is not at issue here. While a judgment of this Court will indeed affect the rights of George Smith, the rights of Nemin are not implicated. Second, although Nemin is a party to several multilateral treaties that this Court must construe, Nemin’s rights will not be affected because a decision of the Court “has no binding force except between the parties” to the case.<sup>29</sup> Thus, Nemin’s meager connections do not form the basis of the dispute.

2. The multilateral treaty reservation is not applicable in this case.

The multilateral treaty reservation protects states such as Kuraca from having the terms of a treaty construed with regard to itself, while other parties to the same treaty are able to assert the non-binding nature of any judgment of this Court as a defense for non-compliance with the Court’s construction of a treaty.<sup>30</sup> This Court has explained that there is no danger of prejudice

<sup>25</sup> East Timor (Port. v. Austl.), 1995 I.C.J. 90, 105 (June 30).

<sup>26</sup> *East Timor*, 1995 I.C.J. at 105.

<sup>27</sup> See Comp. ¶ 25; Clar. ¶ 9.

<sup>28</sup> See Clar. ¶ 8.

<sup>29</sup> I.C.J. Statute, *supra* note 1, art. 59.

<sup>30</sup> See STANIMIR A. ALEXANDROPOV, RESERVATIONS IN UNILATERAL DECLARATIONS ACCEPTING THE COMPULSORY JURISDICTION OF THE INTERNATIONAL COURT OF JUSTICE 112-19

to parties of a case or to absent parties when the Court merely construes customary international law codified in multilateral treaties.<sup>31</sup> Thus, this reservation is inapplicable as the treaties at issue are codifications of customary international law.<sup>32</sup>

## **II. KURACA HAS JURISDICTION UNDER INTERNATIONAL LAW TO APPLY KURACAN NATIONAL HEALTH LAW 1006 TO MEGACEUTICAL-SENHAVA.**

Despite the fact that Senhava bears the burden for proving that the extraterritorial application of the Kuracan National Health Law (“Health Law”) is illegal,<sup>33</sup> Kuraca advances three independent bases of jurisdiction for its extraterritorial application of the law: 1) the subjective territoriality principle, 2) the universality principle, and 3) the nationality principle. Kuraca’s application of its law under these bases is reasonable. Furthermore, the Treaty on Amity and Commerce (“TAC”) does not affect Kuraca’s ability to assert jurisdiction over M-S.

### **A. Kuraca has jurisdiction under the subjective territoriality principle.**

According to the subjective territoriality principle, Kuraca has jurisdiction over infractions “commenced within the state, but completed or consummated abroad.”<sup>34</sup> The vaccine trials regulated by the Health Law fit squarely within this definition. While the trials were conducted in Senhava through M-S, planning and substantial research was no doubt done at the

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(1995).

<sup>31</sup> *See* Military and Paramilitary Activities in and Against Nicaragua (Nicar. v. U.S.), 1986 I.C.J. 14, 94-96 (June 27).

<sup>32</sup> *See infra* Parts III.A., III.B.3.

<sup>33</sup> *See* S.S. Lotus, 1927 P.C.I.J. (ser. A) No. 10, at 18.

<sup>34</sup> IAN BROWNLIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 303-04 (5th ed. 1998); INTERNATIONAL LAW ASSOCIATION, REPORT OF THE FIFTY-FIFTH CONFERENCE 139 (1972); RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 402 (1987) [hereinafter RESTATEMENT].

company's headquarters in Kuraca, where its principal laboratories and drug processing facilities are located.<sup>35</sup> Indeed, Megaceutical initiated the idea for the MHVD vaccine project and hired Dr. Maria Yukawa-Lopez to head the project.<sup>36</sup> Most importantly, Megaceutical controls all of its Senhavan satellite's "small scale"<sup>37</sup> operations through a shareholder agreement.<sup>38</sup> Megaceutical's orchestration of the vaccine trials is also analogous to previous applications of the subjective territoriality principle where states asserted jurisdiction based on the planning of, or even a single act of, a fraudulent transaction occurring within its territory.<sup>39</sup>

**B. Kuraca has jurisdiction under the universality principle.**

The universality principle allows jurisdiction over foreign nationals "where the circumstances . . . justify the repression of some types of crime as a matter of international public policy."<sup>40</sup> International human rights law has gained such stature that some scholars comment that "the principle of sovereignty is not necessarily a bar to intervention within another nation's domestic affairs regarding the protection of international human rights."<sup>41</sup> Thus, this Court should permit Kuraca to apply its law extraterritorially under the universality principle in order to

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<sup>35</sup> See Comp. ¶ 9.

<sup>36</sup> See *id.* ¶ 12.

<sup>37</sup> *Id.* ¶ 9.

<sup>38</sup> See *id.* ¶ 10.

<sup>39</sup> See *Libman v. The Queen*, [1985] 2 S.C.R. 178, 212-13 (Can.); see also *Leasco Data Processing Equip. Corp. v. Maxwell*, 468 F.2d 1326, 1334 (2nd Cir. 1972).

<sup>40</sup> See BROWNIE, *supra* note 34, at 307.

<sup>41</sup> William C. Plouffe, *Sovereignty in the "New World Order": The Once and Future Position of the United States, A Merlinesque Task of Quasi-legal Definition*, 4 TULSA J. COMP. & INT'L L. 49, 59-60 (footnote omitted) (1996); see also discussion *supra* Part I.A.1 and discussion *infra* Part III.A.

prevent further human rights abuses in Senhava.<sup>42</sup>

**C. Kuraca has jurisdiction under the nationality principle.**

The nationality principle “is also generally recognized as a basis for jurisdiction over extra-territorial acts.”<sup>43</sup> Thus, Kuraca should be able to apply its Health Law to M-S because it is a national of Kuraca.

1. General principles of international law hold that a subsidiary corporation should be treated as a national of the country from which its parent corporation controls it.

The nationality of a parent corporation determines the nationality of a subsidiary corporation in many contexts, especially when the parent controls the affairs of the subsidiary. Numerous international agreements cite the controlling parent corporation’s nationality as the determining factor,<sup>44</sup> and various courts have held it determinative of the subsidiary’s nationality.<sup>45</sup> Furthermore, in an analogous situation, countless courts have based liability of a

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<sup>42</sup> See *infra* Part III.B.3.

<sup>43</sup> See BROWNLIE, *supra* note 34, at 306.

<sup>44</sup> See, e.g., 1982 U.N. Convention on the Law of the Sea, *opened for signature* Dec. 10, 1982, art. 153, para. 2, 1833 U.N.T.S. 33, 455; Declaration of the Government of the Democratic and Popular Republic of Algeria Concerning the Settlement Claims by the Government of the United States of America and the Government of the Islamic Republic of Iran, Jan. 19, 1981, art. vii, para. 1, 1 Iran-U.S. Cl. Trib. Rep. 9, 11 (1983), 20 I.L.M. 223, 232-33 (1981); Convention on the Settlement of Investment Disputes between States and Nationals of other States, *opened for signature* Mar. 18, 1965, art. 25, 575 U.N.T.S. 159, 174; Draft Convention Concerning Recognition of the Legal Personality of Foreign Companies (Societies), Associations, and Foundations, *opened for signature* Oct. 31, 1951, art. II, 40 *Revue Critique de Droit International (Fr.)* 724, *reprinted in* 1 AM. J. COMP. L. 277, 277-78 (1952). Cf. Convention Relating to the Mutual Recognition of Companies and Legal Persons, Feb. 29, 1968, art. 3-5, 2 *Common Mkt. Rep. (CCH)* 5211 (1968).

<sup>45</sup> See, e.g., *Societe Magnet & Garuz v. X*, Cour d’appel de Montpellier, May 3, 1926 [1926], S. Jur.II. 75 (Fr.); *Daimler Co. v. Continental Tyre & Rubber Co. (Great Britain) Ltd.*, [1916] 2 App. Cass. 307, 340-41 (H.L.) (Eng.); *Societe W. Canadian Collieries v. Vanverts*, Tribunal civil de Lille, May 21, 1908, [1910], D. P. II. 41 (Fr.).

parent corporation on its control of a subsidiary.<sup>46</sup> Thus, given Senhava's concession that Megaceutical effectively controls M-S,<sup>47</sup> the subsidiary is a national of Kuraca.

While section 213 of the *Restatement (Third) of the Foreign Relations Law of the United States* ("Restatement") seems to indicate that a corporation's nationality should be determined by its state of incorporation,<sup>48</sup> this rule is not absolute. For example, the comments to section 213 explain that "[a] state cannot, by requiring a foreign enterprise to incorporate locally, compel the enterprise to surrender . . . protection by the state of its parent corporation."<sup>49</sup> Accordingly, as M-S is required under Senhavan law to incorporate in Senhava,<sup>50</sup> the *Restatement* is inapplicable.

2. *Barcelona Traction* is inapplicable under the facts of this case.

In *Barcelona Traction*, this Court held that a corporation's nationality should be determined by "the laws of which it is incorporated and in whose territory it has its registered office."<sup>51</sup> However, the corporation in *Barcelona Traction* had free choice in selecting its country of incorporation,<sup>52</sup> whereas, M-S was forced to incorporate in Senhava.<sup>53</sup> But most

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<sup>46</sup> See, e.g., *Denty v. SmithKline Corp.*, 907 F. Supp. 879 (E.D. Pa. 1995); Case 202/85, Commission Decision of 19 December 1984 relating to a Proceeding Under Article 85 of the EEC Treaty (Wood Pulp), 1985 O.J. (L 85) 1; *Mas Marques v. Digital Equip. Corp.*, 490 F. Supp. 56, 58 (D. Mass. 1980); *Joined Cases 6 & 7/73, Instituto Chemioterapico Italiano SpA & Commercial Solvents Corp. v. Commission*, 1974 E.C.R. 223; *Case 48/69, Imperial Chem. Indus., Ltd. v. E.E.C. Commission* 1972 E.C.R. 619, 662.

<sup>47</sup> See Comp. ¶¶ 10, 31.

<sup>48</sup> See RESTATEMENT, *supra* note 34, § 213.

<sup>49</sup> *Id.* cmt. 3.

<sup>50</sup> See Comp. ¶ 10.

<sup>51</sup> *Barcelona Traction, Light, and Power Co. (Belg. v. Spain)*, 1970 I.C.J. 3, 42 (Feb. 5).

<sup>52</sup> See *Barcelona Traction*, 1970 I.C.J. at 42.

<sup>53</sup> See Comp. ¶ 10.

importantly, the corporation in *Barcelona Traction* had a “close and permanent connection” with its state of incorporation,<sup>54</sup> as opposed to the tenuous ties between M-S and Senhava.

**D. Kuraca’s application of Kuracan National Health Law 1006 is reasonable.**

The *Restatement* requires any assertion of jurisdiction be “reasonable” in addition to satisfying one of the traditional grounds for jurisdiction.<sup>55</sup> The reasonableness of Kuraca’s extraterritorial assertion of its Health Law is evident in that: 1) The drug testing has a strong link to Kuraca resulting from Megaceutical’s control of the tests;<sup>56</sup> 2) the nationality of the individual being regulated is Kuracan;<sup>57</sup> and 3) human rights are a serious national concern within Kuraca, as well as on an international scale.<sup>58</sup> This is true despite the fact that the reasonableness standard is not binding on Kuraca, as it does not properly reflect international law.<sup>59</sup>

**E. The Treaty of Amity and Commerce does not prevent Kuraca from applying the National Health Law extraterritorially.**

Though the TAC states that Kuraca and Senhava submit “themselves to all laws and regulations applicable to them,”<sup>60</sup> this does not preclude Kuraca’s extraterritorial application of its law due to Senhava’s prior material breach of the treaty. When the Health Law first affected

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<sup>54</sup> *Barcelona Traction*, 1970 I.C.J. at 42.

<sup>55</sup> See RESTATEMENT, *supra* note 34, § 403.

<sup>56</sup> See Comp. ¶¶ 10, 31.

<sup>57</sup> See *supra* Part II.C.

<sup>58</sup> See Kuracan National Health Law, 1006 § 6(a)(1); see also discussion *supra* Parts I.A.1., II.B.

<sup>59</sup> See David B. Massey, *How the American Law Institute Influences Customary Law: The Reasonableness Requirement of the Restatement of Foreign Relations Law*, 22 YALE J. INT’L L. 419, 444 (1997).

<sup>60</sup> Clar. ¶ 10.

M-S, the law conflicted with no Senhavan laws. Only in reaction to the Health Law did the Senhavan government begin treating M-S as if it was acting illegally. Indeed, Senhava attempted to force M-S to conduct drug trials via a government order, threatened its officers with substantial fines and imprisonment, and eventually shut the company down.<sup>61</sup> This treatment constitutes material breach of the treaty in that Senhava did not permit M-S, a Kuracan national, to carry on trade “upon the same terms as Senhava’s nationals are permitted to” in Kuraca.<sup>62</sup> It is reasonable to infer that Senhavan companies operating in Kuraca have been treated well based on the countries’ thirty-two year history of normal trading relations.<sup>63</sup> Thus, the Vienna Convention permits Kuraca to suspend the treaty’s operation and apply its Health Law extraterritorially.<sup>64</sup>

### **III. KURACA MUST APPLY NATIONAL HEALTH LAW 1006 REGARDING BIOMEDICAL RESEARCH ON HUMANS TO MEGACEUTICAL AND ITS SUBSIDIARY BECAUSE IT EMBODIES INTERNATIONAL LAW.**

#### **A. Human rights are a matter of international concern and are governed by international law.**

International law protects human rights. Since at least the end of the Second World War, the international system has transformed from one which values state sovereignty above all else to one which recognizes that there are inviolable human rights involving the dignity and integrity of people that no state may violate.<sup>65</sup> The United Nations Charter, a clear indicator of the international protection afforded to human rights, reaffirms in its preamble “faith in fundamental

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<sup>61</sup> See Comp. ¶ 30.

<sup>62</sup> See Clar. ¶ 10.

<sup>63</sup> See *id.* ¶ 2.

<sup>64</sup> See Vienna Convention, *supra* note 13, art. 60, 1155 U.N.T.S. at 346.

<sup>65</sup> See Louis Henkin, *Human Rights and State “Sovereignty,”* 25 GA. J. INT’L & COMP. L. 31, 33-34 (1995/1996).

human rights [and] in the dignity and worth of the human person.”<sup>66</sup> Both Senhava and Kuraca are members of the United Nations (“U.N.”) and are bound by the provisions of the Charter. Further, the U.N.’s Universal Declaration of Human Rights, which guarantees equality in dignity and rights,<sup>67</sup> embodies customary international law.<sup>68</sup> The Convention on the Elimination of All Forms of Discrimination Against Women (“CEDAW”),<sup>69</sup> the Convention Against Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment (“CAT”),<sup>70</sup> and the Convention on the Rights of the Child (“CRC”),<sup>71</sup> key human rights treaties that guarantee human dignity and to which Senhava and Kuraca are parties, also embody customary international law.<sup>72</sup>

**B. International law prohibits conducting the MHVD Biomedical Research Protocol in Senhava.**

Because the Research Protocol violates multilateral human rights treaties, customary international law, and customary international human rights law, this Court should uphold Kuraca’s rejection of the MVHD vaccine trials in Senhava.

1. Treaties to which Senhava and Kuraca are parties prohibit the Research Protocol.

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<sup>66</sup> U.N. CHARTER preamble.

<sup>67</sup> U.N. G.A. Res. 217, U.N. GAOR, 3d Sess., U.N. Doc. A/810 (1948).

<sup>68</sup> See, e.g., Montreal Statement of the Assembly for Human Rights (1968), *reprinted in* 9 J. INT’L COMM. JURISTS REV. 94 (1968); Declaration of Tehran, Final Act of the International Conference on Human Rights, U.N. Doc. A/CONF.32/41 (1968), *reprinted in* UNITED NATIONS, HUMAN RIGHTS, A COMPILATION OF INTERNATIONAL INSTRUMENTS 43 (1988).

<sup>69</sup> See CEDAW, *supra* note 3, 1249 U.N.T.S. 13.

<sup>70</sup> See CAT, *supra* note 3, 1465 U.N.T.S. 113.

<sup>71</sup> See Convention on the Rights of the Child, *opened for signature* Nov. 20, 1989, 1577 U.N.T.S. 3 [hereinafter CRC].

<sup>72</sup> See *supra* notes 67, 68.

The CEDAW, the CAT and the CRC all guarantee human dignity and integrity.<sup>73</sup>

Advances in biomedics and life sciences may undermine these guarantees, thereby invoking the application of these human rights treaties when conducting human experimentation.<sup>74</sup> The World Conference on Human Rights officially links medical ethics with human rights based on the ways in which ethics and health sciences concern fundamental questions throughout the world with regard to all humans.<sup>75</sup> The Research Protocol violates the guarantee of human dignity and integrity because it does not provide for free and informed consent, as it targets the most vulnerable populations of Senhava.<sup>76</sup>

The Research Protocol also violates specific human rights protections ensured in the CEDAW, the CAT and the CRC. The CEDAW provides for the elimination of “all forms of discrimination and . . . promot[ing] equal rights for men and women.”<sup>77</sup> Because the Protocol targets women in maternal clinics, it violates the CEDAW by discriminatorily targeting women in health clinics to the dangerous Vaccine 078c. The CAT prohibits states from, among other things, treating people in cruel, inhuman or degrading ways.<sup>78</sup> Subjecting disadvantaged populations to the random risk of suffering from debilitating asthma is degrading and

<sup>73</sup> See CEDAW, *supra* note 3, preamble, 1249 U.N.T.S. at 14; CAT, *supra* note 3, preamble, 1465 U.N.T.S. at 113; CRC, *supra* note 71, preamble, 1577 U.N.T.S. at 44.

<sup>74</sup> See Sonia Le Bris et al., *International Bioethics, Human Genetics, and Normativity*, 33 HOUS. L. REV. 1363, 1364-65 (1997); Vienna Declaration and Program of Action, U.N. GAOR, 48th Sess., pt. I, 22d mtg.P11, U.N. Doc. A/CONF.157.24 (1993), 32 I.L.M. 1661, 1667 (1993).

<sup>75</sup> See Le Bris et al., *supra* note 74, at 1364-65; Jean-Louis Baudouin, *Reflexions sur les Rapports de la Bioethique et des Droits Fondamentaux*, in ETHIQUE ET DROITS FONDAMENTAUX 147, 149 (Guy LaFrance ed., 1989).

<sup>76</sup> See *infra* Part III.B.3.c.

<sup>77</sup> CEDAW, *supra* note 3, preamble, 1249 U.N.T.S. at 13.

<sup>78</sup> CAT, *supra* note 3, art. 16, 1465 U.N.T.S at 116.

inhuman—sacrificing their bodily integrity and human worth without first securing their free and informed consent. The introductory note to the CRC states that the CRC is intended to encompass the “protection of children . . . against medical experimentation.”<sup>79</sup> This language was not specifically included in the treaty—though clearly within the scope of it—because of the “last minute rush” in preparing the final version of the CRC.<sup>80</sup> The Protocol violates the intent of the CRC because it specifically targets children in health clinics and orphans.<sup>81</sup>

2. The Convention on Human Rights and Biomedicine prohibits the Research Protocol.

The Convention on Human Rights and Biomedicine (“CHRB”) reiterates that human rights protect human dignity.<sup>82</sup> Article 5 declares that “intervention in the health field may only be carried out after the person concerned has given *free and informed consent* to it.”<sup>83</sup> Article 16 requires the satisfaction of five conditions before research may be conducted on humans. One of these conditions restates Article 5, thereby emphasizing its importance. Another condition is approval of the research project by a “competent body after independent examination.”<sup>84</sup> The Research Protocol violates the voluntary, informed consent provisions of Articles 5 and 16, and it violates Article 16's requirement of a competent ethics review board. As discussed in Part III.B.3.c., the targeted research populations are also Senhava's most vulnerable, thereby

<sup>79</sup> Convention on the Rights of the Child, Introductory Note, U.N. Doc. E/CN.4/1989/48 (1989), 28 I.L.M. 1448,1451 n.22.

<sup>80</sup> *See id.*

<sup>81</sup> *See Comp.* ¶ 15.

<sup>82</sup> *See* Convention on Human Rights and Biomedicine, *opened for signature* Apr. 4, 1997, preamble, 36 I.L.M. 817, 821 [hereinafter CHRB].

<sup>83</sup> *Id.* art. 5, at 821 (emphasis added).

<sup>84</sup> *Id.* art. 16, at 822.

undermining the possibility of any voluntary, informed consent. Further, Senhava has no ethics review board, much less a competent one, and Kuraca's ethics review board has banned the Research Protocol.<sup>85</sup>

Senhava and Kuraca have signed the CHRB, and their ratifications are pending.<sup>86</sup> Therefore, Article 18 of the Vienna Convention, to which Senhava and Kuraca are parties, obligates them to "refrain from acts which would defeat the object and purpose of a treaty" because they have "signed the treaty."<sup>87</sup> Conducting research trials which directly violate specific provisions of the CHRB and which undermine its preamble's stated purpose of respecting human dignity would defeat the object and purpose of the CHRB.

3. The Research Protocol violates customary international law and customary international human rights law because it does not ensure adequate informed consent and because it does not provide for an ethics review board.
  - a. *There is a lower threshold for establishing customary international human rights law, as opposed to customary international law.*

Generally, to prove the existence of a norm as customary international law, the norm must be 1) an identifiable state practice and 2) recognized as obligatory and legally binding.<sup>88</sup> In *North Sea Continental Shelf*, this Court found that multilateral conventions may generate rules which crystallize customary international law after meeting certain conditions: 1) the rule must be of a "norm-creating character such as could be regarded as forming the basis of a general rule

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<sup>85</sup> See Comp. ¶ 23.

<sup>86</sup> See *id.* ¶ 3.

<sup>87</sup> Vienna Convention, *supra* note 13, art. 18, 1155 U.N.T.S. at 336; see also Comp. ¶ 3.

<sup>88</sup> See *North Sea Continental Shelf (FRG/Den.; FRG/Neth.)*, 1969 I.C.J. 3, 43-44 (Feb. 20).

of law;” 2) there must be widespread participation in the Convention, particularly those states whose interests are specifically affected; and 3) there must be *opinio juris* reflected in near uniform State practice, though “the passage of only a short period of time is not necessarily, or of itself, a bar to the formation of a new rule of customary international law.”<sup>89</sup>

In the realm of human rights, however, the standard for establishing customary international law is different. In *Military and Paramilitary Activities in and against Nicaragua*, this Court emphasized *opinio juris* as the crux of establishing law with regard to protecting humans.<sup>90</sup> Section 701 of the *Restatement* states that “the practice of states that is accepted as building customary international law of human rights includes some forms of conduct different from those that build customary international law generally”;<sup>91</sup> “it is not based on consent . . . it does not honor or accept dissent, and it binds particular states regardless of their objection.”<sup>92</sup>

- b. *Customary international law and customary international human rights law require voluntary, informed consent and a competent ethics review board when conducting biomedical research.*
  - i. The Convention on Human Rights and Biomedicine embodies customary international law and customary international human rights law requiring informed consent and an ethics review board.

Even if Senhava and Kuraca were not bound to further the object and purpose of the

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<sup>89</sup> *North Sea Continental Shelf*, 1969 I.C.J. at 41-42. See also SIR IAN SINCLAIR, *THE VIENNA CONVENTION ON THE LAW OF TREATIES* 22 (1984).

<sup>90</sup> See *Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. U.S.)*, 1986 I.C.J. 14, 98-108 (June 27).

<sup>91</sup> *RESTATEMENT*, *supra* note 34, § 701 n.2.

<sup>92</sup> Henkin, *supra* note 65, at 38.

CHRB,<sup>93</sup> it has become part of customary international law because the provisions of informed consent and an ethics review board do not include any secondary obligations; in other words, they are internationally practiced without any additional conditions, thereby fulfilling *North Sea Continental Shelf*'s first requirement.<sup>94</sup> Second, there is widespread participation in the CHRB; twenty-four of the members of the Council of Europe have signed it, as well as Senhava and Kuraca. Finally, as discussed below, the CHRB reflects *opinio juris*, which independently elevates informed consent and the requirement of an ethics review board to the status of customary international human rights law.

The Explanatory Report to the CHRB states that one of the CHRB's purposes is to "harmonize existing standards":<sup>95</sup> It builds on human rights law that already exists. The CHRB further states that it is consistent with International Covenant on Economic, Social and Cultural Rights<sup>96</sup> and the CRC, treaties which are currently in force and to which Senhava is a party.<sup>97</sup> By signing the CHRB, Senhava and Kuraca indicated their intent to be bound and their belief that they should be bound by the CHRB's provisions.<sup>98</sup> As such, the CHRB constitutes *opinio juris*.

ii. The Declaration of Helsinki and the Nuremberg Code are

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<sup>93</sup> See discussion *supra* Part III.B.2.

<sup>94</sup> See *North Sea Continental Shelf*, 1969 I.C.J. at 41.

<sup>95</sup> Explanatory Report to the Convention on Human Rights and Biomedicine, *authorized* Dec. 17 1996, 36 I.L.M. 826, 827 (emphasis added).

<sup>96</sup> *open for signature* Dec. 16, 1966, 993 U.N.T.S. 3, 5.

<sup>97</sup> See CHRB, *supra* note 82, preamble, 36 I.L.M. at 821.

<sup>98</sup> See *Nicaragua*, 1986 I.C.J. at 98-108; RESTATEMENT, *supra* note 34, § 701 n.2; Hurst Hannum, *The Status of the Universal Declaration of Human Rights in National and International Law*, 25 GA. J. INT'L & COMP. L. 287, 318-20 (1995/1996); Henkin, *supra* note 65, at 36-38; THEODOR MERON, HUMAN RIGHTS AND HUMANITARIAN NORMS AS CUSTOMARY LAW 108-13 (1989).

customary international human rights law requiring informed consent and an ethics review board.

The Nuremberg Code<sup>99</sup> and the World Medical Association Declaration of Helsinki<sup>100</sup> (“Declaration of Helsinki”) reflect *opinio juris*. The Nuremberg Code consists of ten principles, articulated in the final judgment of the trial of Nazi doctors who were indicted for and convicted of crimes against humanity committed during World War II.<sup>101</sup> The first principle is: “The voluntary consent of the human subject is absolutely essential.”<sup>102</sup> The Nuremberg Code has been described as “[t]he most complete and authoritative statement of the law of informed consent” and “part of international common law . . . [which] may be applied in both civil and criminal cases.”<sup>103</sup>

The Declaration of Helsinki builds on the Nuremberg Code.<sup>104</sup> In addition, it implements the requirement of an ethics review board.<sup>105</sup> Both are “widely known international codes of

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<sup>99</sup> *Tribunals of War Criminals before the Nuremberg Military Tribunals Under Control Council Law No. 10*, Vols. I and III (Washington D.C.: U.S. Government Printing Office, 1949), Vol. II, 181 [hereinafter Nuremberg Code].

<sup>100</sup> WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI V, 48th World Medical Assembly, Somerset, South Africa, 1996 [hereinafter Declaration of Helsinki].

<sup>101</sup> See Michael A. Grodin, *Historical Origins of the Nuremberg Code*, in THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 121, (George J. Annas & Michael A. Grodin eds., 1992) [hereinafter NAZI DOCTORS].

<sup>102</sup> Nuremberg Code, *supra* note 99.

<sup>103</sup> GEORGE J. ANNAS ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION 1 (1977); see also 4 ENCYCLOPEDIA OF BIOETHICS 1746-82 (Warren Reich ed., 1978).

<sup>104</sup> See Declaration of Helsinki, *supra* note 100, art. I.9.

<sup>105</sup> See *id.* art. I.2.

ethics for the protection of human subjects.”<sup>106</sup> International texts and legislation recognize the Declaration of Helsinki as international law regarding human experimentation, and medical organizations accept it internationally.<sup>107</sup> It has also been cited as constituting the basis of “universality in the field of ethical-moral standards in human experimentation.”<sup>108</sup>

The Nuremberg Code and the Declaration of Helsinki are modern clarifications of medical ethics followed worldwide, necessary because of advances in medicine heralded with new technology and the internationalization of disease caused by increased international travel.<sup>109</sup> Indeed, the Nuremberg Code has its ethical roots in Percival’s code of medical ethics, requiring researchers to be conscientious and responsible, and in Beaumont’s code of medical ethics, requiring the same, as well as a statement of voluntary, informed consent. It builds on the Hippocratic oath, which obligates doctors to do no harm to their patients.<sup>110</sup> More modern manifestations of the Nuremberg Code and the Declaration of Helsinki include the International

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<sup>106</sup> Ileana Dominquez-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT’L L. J. 245, 273 (1997).

<sup>107</sup> See Sharon Perley et al., *The Nuremberg Code: An International Overview*, in NAZI DOCTORS, *supra* note 101, at 159 (citing M. Cheriff Bassiouni et al., *An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation*, 72 J. CRIM. L. & CRIMINOLOGY 1587, 1611 (1981)).

<sup>108</sup> *Id.* at 160 (citing William Curran, *Subject Consent Requirements in Clinical Research: An International Perspective for Industrial and Developing Countries*, in HUMAN EXPERIMENTATION AND MEDICAL ETHICS (Zbigniew Bankowski & Norman Howard-Jones eds., 1982)).

<sup>109</sup> See David P. Fidler, *The Globalization of Public Health: Emerging Infectious Diseases and International Relations*, 5 IND. J. GLOBAL LEGAL STUD. 11, 14-15 (1997).

<sup>110</sup> Grodin, *supra* note 101, at 124-26.

Covenant on Civil and Political Rights, which requires voluntary consent,<sup>111</sup> the Principles for Those in Research and Experimentation, which requires informed consent,<sup>112</sup> the International Ethical Guidelines for Biomedical Research Involving Human Subjects, issued by the Council for International Organizations of Medical Sciences in collaboration with the WHO (“WHO/CIOMS Guidelines”) and requiring informed consent as well as approval of an ethics review board,<sup>113</sup> and many other international instruments.<sup>114</sup>

c. *The Research Protocol does not ensure voluntary, informed consent, and it does not provide an ethics review board.*

The WHO/CIOMS Guidelines define vulnerable populations as those having “a substantial incapacity to protect [their] own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group.”<sup>115</sup> The Research Protocol targets the most vulnerable peoples of Senhava—prisoners, people in outer island villages, orphans, and women and children in health clinics.<sup>116</sup> These are the people who have the least freedom of choice and who are most vulnerable to manipulation, particularly when

<sup>111</sup> International Covenant on Civil and Political Rights, *opened for signature* Dec. 19, 1966, art. 7, 999 U.N.T.S. 171, 175.

<sup>112</sup> Principles for Those in Research and Experimentation, World Medical Assembly, 8th Assembly (Sept.-Oct. 1954), *reprinted in Organizational News*, 2 WORLD MED. J. 12, 14 (1955).

<sup>113</sup> See THE COUNCIL FOR INT’L ORG. OF MED. SCIENCES IN COLLABORATION WITH THE WORLD HEALTH ORG., INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS, *reprinted in HUMAN EXPERIMENTATION AND MEDICAL ETHICS*, *supra* note 108, at 387 [hereinafter WHO/CIOMS GUIDELINES].

<sup>114</sup> See Kevin King, *A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STAN. J. INT’L L. 163, 170-90.

<sup>115</sup> WHO/CIOMS GUIDELINES, *supra* note 113, at 11.

<sup>116</sup> See Comp. ¶ 15.

M-S uses the Senhavan police to “provide transportation” to M-S personnel—truly undermining the possibility of free consent and constituting coercion and duress.<sup>117</sup>

It is unlikely that prisoners would ever be able to give informed consent because often they have been confined in isolation for so long or to such an extent that they are not able to weigh options in a meaningful way, as free citizens are able to do.<sup>118</sup> Further, because they are forcibly deprived of their freedom, they often experience a significant lack of self-esteem and diminished capacities for decision-making.<sup>119</sup> Prisoners may “consent” to medical research to escape from the violent atmosphere of most prisons to a more regulated and protected environment provided through medical experimentation.<sup>120</sup> They may simply stop caring about their own well-being—defeated and discouraged by prison life—and helplessly “consent” to medical experimentation.<sup>121</sup> Further, if a cure is found for MHVD, with or without the use of prisoners, it is unlikely that they will be one of the groups to benefit from the use of any such vaccine, thereby increasing their exploitation.<sup>122</sup>

People in outer island villages do not share the same basis of knowledge and education with populations residing in more developed areas; they are therefore unable to give informed consent. Traditionally, isolated populations—especially isolated populations in developing

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<sup>117</sup> *See id.*

<sup>118</sup> *See* Simon N. Verdun-Jones et al., *Prisoners as Subjects of Biomedical Experimentation: Examining the Arguments For and Against a Total Ban*, in RESEARCH ON HUMAN SUBJECTS 503, 506 (David N. Weisstub ed., 1998).

<sup>119</sup> *See id.*

<sup>120</sup> *See id.* at 521-22.

<sup>121</sup> *Id.* at 522.

<sup>122</sup> *Id.* at 523.

countries like Senhava—lack a scientific conception of disease and a comprehension of the technical details of proposed research.<sup>123</sup> The peculiar qualities of remote, isolated villages make the Protocol’s “informed” Consent Form completely inadequate; indeed, it is a tool for exploitation.

Conducting the Research Protocol on orphans and women and children in health clinics exploits Senhavans who are in desperate situations and who are least able to freely decline taking part in trials that are sponsored, promoted and apparently required by the Senhavan government.<sup>124</sup> The Consent Form’s provision allowing a legally responsible person to give consent for a minor is especially problematic with respect to orphans because Senhava may be the legally responsible authority that provides consent for such testing.

With respect to all of the vulnerable populations discussed above, there is a further problem involving the use of placebos. Assuming, *arguendo*, that the targeted groups could give informed consent, such consent would cease to be informed when they are given placebos because the Consent Form does not mention that placebos may be used.<sup>125</sup> The groups have never consented to the possibility of ingesting placebos. Naturally, another immediate problem follows: If the targeted populations believe that they are being treated by a vaccine, then they may continue to engage in conduct which actually spreads the disease.

Finally, the Research Protocol does not provide for a biomedical ethics review board to evaluate the Protocol, thereby violating customary international law and customary international

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<sup>123</sup> Carel B. Ijsselmuiden & Ruth R. Faden, *Medical Research and the Principle of Respect for Persons in Non-Western Cultures*, in NAZI DOCTORS, *supra* note 101, at 286-87.

<sup>124</sup> See Comp. ¶ 15.

<sup>125</sup> See Christian Mormont, *Ethical Questions Pertaining to the Use of Placebos*, in RESEARCH ON HUMAN SUBJECTS, *supra* note 118, at 541-42.

human rights law.

#### IV. SENHAVA MUST IMMEDIATELY RELEASE GEORGE SMITH BECAUSE HIS DETENTION VIOLATES INTERNATIONAL LAW.

Because the Republic of Nemin, of which George Smith is a citizen, has declined to intervene in the case at bar or to otherwise participate in the proceedings,<sup>126</sup> Kuraca has jurisdiction to demand the immediate release of Smith from detention in Senhava. If Kuraca did not assert his claims, Smith would be left without a remedy. Further, Smith's status as an agent of the Kuracan Medical Product Regulation Agency creates a bond between Kuraca and Smith, thereby giving Kuraca an interest in asserting Smith's rights.<sup>127</sup>

Further, Senhava has violated Smith's rights under international law. Article 10 of the Universal Declaration of Human Rights, which constitutes customary international law,<sup>128</sup> states that "[e]veryone is entitled in full equality to a fair and public hearing by an independent and impartial tribunal, in the determination of his rights and obligations and of any criminal charge against him." Senhavan authorities are holding Smith without bail; they have presented no formal charges against him; they have not scheduled a trial date.<sup>129</sup> Senhavan authorities arrested Smith for performing duties that Senhava previously agreed he should perform.<sup>130</sup> Therefore, his subsequent arrest for performing precisely these duties is also arbitrary, thereby violating Article 9 of the Universal Declaration of Human Rights.

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<sup>126</sup> See Comp. ¶ 11.

<sup>127</sup> See J. BRIERLY, THE LAW OF NATIONS 276-87 (6th ed., 1963); see also Comp. ¶ 11.

<sup>128</sup> See discussion *supra* Part III.A.

<sup>129</sup> See Comp. ¶ 25.

<sup>130</sup> See *id.* ¶ 11.

**V. SENHAVA SHOULD PAY COMPENSATION FOR INJURIES CAUSED BY ITS BREACHES OF INTERNATIONAL LAW.**

Customary international law dictates that Senhava should remedy its breaches<sup>131</sup> of the TAC the CEDAW, the CAT, the CRC, and customary international law.<sup>132</sup> Thus, Senhava should pay compensation for injuries caused and cease all conduct that resulted in the breaches. Furthermore, a state may recover for injuries to its nationals, such as Megaceutical, M-S,<sup>133</sup> and the Kuracan shareholders of M-S.<sup>134</sup> Therefore, Senhava should compensate Kuraca for Megaceutical's advance payment of Euros 2,000,000 and for all damages arising from M-S's closing.

**CONCLUSION AND PRAYER FOR RELIEF**

For the foregoing reasons, Kuraca respectfully requests this Honorable Court to assert jurisdiction over the subject matter of this case; find that Kuraca properly applied its National Health Law 1006 to M-S in compliance with international law; order the immediate release of George Smith; declare that Kuraca incurred no liability to Senhava in this matter; and order Senhava to rescind the order closing the offices of M-S and to return the advance payment of 2,000,000 Euros to the Senhavan Ministry of Health.

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<sup>131</sup> See U.S. Diplomatic and Consular Staff in Tehran (U.S. v. Iran), 1980 I.C.J. 3, 41-42 (May 24); Reparation for Injuries Suffered in the Service of the United Nations, 1949 I.C.J. 174, 184 (Apr. 11); Corfu Channel (U.K. v. Alb.), 1949 I.C.J. 4, 23-24 (Apr. 9); Chorzow Factory (Germ. v. Pol.), 1928 P.C.I.J. (ser. A) No. 17, at 47.

<sup>132</sup> See *supra* Part III.B.

<sup>133</sup> See *Corfu Channel*, 1949 I.C.J. at 44.

<sup>134</sup> See *Elettronica Sricula S.p.A. (ELSI)* (U.S. v. Italy), 1989 I.C.J. 15, 50 (July 20).

