

## DID DR. ABE SELL HIS SOUL? THE DEFAMATION CASE IN JAPAN'S HIV-TAINTED BLOOD SCANDAL

*Kawakami v. Sakurai*, 1390 SAIBANSHO JIHŌ 313 (Sup. Ct., June 15, 2005)

Translated by Rebecca R. Carlson†

*Translator's Note:* Is Japan a “paradise for the press?”<sup>1</sup> Or is robust discourse on matters of public interest in Japan stifled because of defamation laws that heavily favor the plaintiff? *Kamakami v. Sakurai*, as one of the final events in Japan's HIV-tainted blood scandal, is a provocative and illustrative chapter in the freedom of press and defamation law in Japan.

In the early 1980s, hemophiliacs faced an HIV epidemic. When researchers concluded the HIV virus could be transferred by blood, they recognized that the blood products created from plasma pooled from hundreds of donors used to treat hemophiliacs could carry the HIV virus.<sup>2</sup> Clinical trials soon proved that the HIV virus could be deactivated through a heating process.<sup>3</sup> But in Japan, later investigations revealed delays in clinical trials and in recalls of potentially tainted products by both pharmaceutical companies and the government.<sup>4</sup> Multiple prosecutions and convictions for criminal negligence followed this scandal.<sup>5</sup>

Freelance journalist Yoshiko Sakurai not only followed the investigations, but conducted her own.<sup>6</sup> Based on her extensive research, she published a magazine article and a best-selling book on what has become known as the HIV-tainted blood scandal in Japan.<sup>7</sup> In these publications, Sakurai accused Dr. Takeshi Abe, a highly respected hemophilia specialist and government advisor, of intentionally delaying the clinical trials the pharmaceutical companies commissioned him to conduct for personal monetary gain.<sup>8</sup> Two years after the book's publication, authorities arrested and prosecuted Dr.

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<sup>1</sup> James J. Nelson, *Culture, Commerce, and the Constitution: Legal and Extra-Legal Restraints on Freedom of Expression in the Japanese Publishing Industry*, 15 UCLA PAC. BASIN L.J. 45, 46 (1996) (citing Masao Horibe, *Press Law in Japan*, in PRESS LAW IN MODERN DEMOCRACIES 315, 334 (Pnina Lahav ed., 1985)).

<sup>2</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, *UPDATE: ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) IN PERSONS WITH HEMOPHILIA*, MORBIDITY AND MORTALITY WEEKLY REPORT (1984), available at <http://wonder.cdc.gov/wonder/prevguid/p0000356/p0000356.asp>; see also *infra* Part 2.(3).vi.

<sup>3</sup> Eric A. Feldman, *Blood Justice: Courts, Conflict, and Compensation in Japan, France, and the United States*, 34 LAW & SOC'Y REV. 651, 666 (2000).

<sup>4</sup> Awaji Takehisa, *HIV soshō to wakai*, 1093 JURISUTO 52 (1996), translated in 6 PAC. RIM L. & POL'Y J. 581 (1997) (Keisuke Mark Abe trans., *HIV soshō to wakai*, 1093 JURISUTO 52 (1996)).

<sup>5</sup> *Id.*

<sup>6</sup> See *infra* Part 2.(7).

<sup>7</sup> See *infra* Part 2.(2).

<sup>8</sup> See *infra* Attachment 1.

Abe for professional negligence<sup>9</sup> and Dr. Abe filed a defamation case against Sakurai based on several statements in the article and book.<sup>10</sup>

The unanimous Supreme Court decision handed down in Sakurai's favor, translated below, is significant for what is said, but also for what was left unsaid. Sakurai was ultimately justified in her journalism as the Supreme Court unanimously ruled in her favor.<sup>11</sup> However, while it would not be unusual in a similar case in the United States to have commentary on the ruling supporting the freedom of the press, in this case the absence of such language is noteworthy, despite the constitutional right of freedom of the press in Japan<sup>12</sup> having been an integral part of Sakurai's case.

In Japan, in a defamation case involving a matter of public interest, once the plaintiff establishes injury to reputation (or more accurately, honor), the burden shifts to the defendant to prove the truth of the statement, or adequate reason to believe the truth of the statement at the time of publication.<sup>13</sup> Here, the Court chronicled in detail the advances in HIV-AIDS research, the actions of Dr. Abe during the clinical trials, and Sakurai's research efforts prior to publication.<sup>14</sup> Based on these findings, the Court then decided that there was adequate reason to believe the truth of Sakurai's statements of fact in her publications, and that the statements constituted a valid opinion or commentary based on those facts.<sup>15</sup>

One can analyze this case in at least two different ways. On the one hand, Japanese defamation law, as is, does in fact provide sufficient protection for truly robust debate and criticism with an objective test applicable even to the most highly charged situations. Indeed, the Supreme Court could have labeled Sakurai's statements as defamatory personal attacks instead of a validating them as opinions or commentaries.<sup>16</sup> But the court did not consider the statements defamatory despite the damage to reputation because they were based on facts that could be believed to be true.<sup>17</sup> As Sakurai said of this case after the Supreme Court handed down its decision: "[o]ne aspect of the case was that it threatened to restrict the freedom of reporting. This ruling is a joyous event not just for those involved in the HIV-AIDS scandal but for all involved in journalism in Japan."<sup>18</sup>

On the other hand, *Kawakami v. Sakurai* also illustrates the potentially tenuous or limited nature of freedom of the press in Japan. "Harsh" critical journalism is comparatively uncommon in Japan, and commentators have argued that this may be a result of the legal standards on defamation.<sup>19</sup> The Supreme Court did not use the broader constitutional rights of freedom of press and freedom of conscience to justify the statements of opinion in its analysis.<sup>20</sup> Instead, the fight to justify such statements was arduous, and victory was uncertain: Sakurai lost at the appellate level on the exact same

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<sup>9</sup> *Abe Cleared in Tainted Blood Case*, NIKKEI WEEKLY, Apr. 2, 2001; Awaji, *supra* note 4, at 582 n.9.

<sup>10</sup> *Freelance Journalist Ordered to Pay 4 Million Yen in HIV Libel Case*, DAILY YOMIURI, Feb. 26, 2003, at 2.

<sup>11</sup> See *infra* Part 5.

<sup>12</sup> KENPŌ, art. 21, para. 1.

<sup>13</sup> See MARK D. WEST, SEX, SECRETS, AND SPECTACLE: THE RULES OF SCANDAL IN JAPAN AND THE UNITED STATES 75, 77 (2006).

<sup>14</sup> See *infra* Parts 2.(3)-(7).

<sup>15</sup> See *infra* Part 4.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Journalist Did Not Defame Expert in Tainted Blood Fiasco, Says Supreme Court*, JAPAN TIMES, June 17, 2005.

<sup>19</sup> Colin P. A. Jones, Watch What You Say: Defamation in Japan, 20 TEMP. INT'L & COMP. L.J. 499 (2006) (book review of YOICHIRO HAMABE, MEIYO KISON SAIBAN [Defamation Litigation] (2005)); see also WEST, *supra* note 13, at 110-13.

<sup>20</sup> See *infra* Part 4.

legal test she won on in the Supreme Court.<sup>21</sup> Seen from this perspective, *Kawakami v. Sakurai* raises doubts as to whether Japanese defamation law alone adequately protects journalists who criticize distinguished members of the public.

## Summary

The high court decision against the appellant is reversed in part. Appellee's request for appeal on this point is denied. The costs of the initial appeal to the higher court (kōso) and of the final appeal to the higher courts (jōkoku) will be paid by appellee.

## Reasoning

Concerning the reasons of Kawakami Kazuo and the other attorneys for the appellant for bringing an appeal:

1. In this case, the appellee requested monetary compensation and a published apology for the tort of writing defamatory material about him in a magazine article and a book.
2. A summary of the facts legally established in the high court decision is as follows:

### (1) Interested parties

The appellee is a doctor who specializes in hematology and was vice president of K<sup>22</sup> medical school from 1980-1987. Appellant is a freelance journalist who writes under the name "B."

### (2) The statement in the magazine article and book written by the appellant

Appellant wrote a magazine article entitled "The 'Tokyo HIV Litigation' Trial I Experienced (final part)" (the "magazine article"), which was

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<sup>21</sup> See *infra* Part 3.

<sup>22</sup> *Translator's Note*: In compliance with internal regulations for privacy protection, Japanese courts replace names, apart from the names of attorneys and justices, with a Roman letter before posting decisions online. See E-mail from Akira Tanai, Judge, Osaka District Court, to translator (Nov. 12, 2009, 10:19 PM PST)(on file with translator). Commercial reporters of judicial decisions do not necessarily follow such internal regulations. The translator chose to translate the text as it appears on the Supreme Court's website.

published in the March issue of *Chūō Kōron* in April of 1994. On the same basis, the appellant also wrote a book entitled, “The AIDS Crime: the Hemophiliac Tragedy” (first edition published August 7, 1994) (the “book”). Statements from the article and book are listed in Attachment 1 statements 1-4 (below, each is referred to as statement 1, and so on).

### **(3) Hemophilia, clinical trials, and AIDS**

- i. Hemophilia is a hereditary disease characterized by a lack of or decline in Factor VIII or Factor IX in the blood clotting factor, manifested by difficulty in stopping hemorrhaging. There is no cure for hemophilia, so patients are given blood products with the blood clotting factor as a supplement. As the blood products are based on untreated human blood, it has been discovered that there is a risk of infectious disease. In 1983, a large portion of the untreated blood that was used came from the United States and other foreign countries.
- ii. In Japan, manufacturing approval for an unheated, densely concentrated Factor VIII blood clotting product (“unheated product”) was approved in August 1, 1978, but five companies—L company (“L”), M company (“M”), N company (“N”), O corporation (“O”), and P company (“P”)—were not given manufacturing approval until July 1, 1985, to make densely concentrated heated Factor VIII blood clotting product (“heated blood product”) in order to inactivate viruses. Thereafter, Q company (“Q”) was given manufacturing approval on March 1, 1986, and R company (“R”) was given approval on November 19 of the same year—altogether, seven pharmaceutical companies were given approval to make heated blood product (together, the “seven pharmaceutical companies”).
- iii. In order to receive manufacturing approval of medical supplies, manufacturers had to submit data related to test results of clinical trials and other data in the written application. The purpose of the clinical trials was to gather data together from the above-mentioned test results from clinical studies. Generally, the clinical trials were divided into three tests: Test 1, Test 2, and Test 3. Test 1 was administered to investigate the safety, etc., of products, and was conducted on a limited number of healthy male volunteers. Test 2 was administered to test effectiveness, safety, and other matters, and appropriate medical supplies were given to a limited number of patients. Test 3 was

- conducted on select patients based on the data obtained from Tests 1 and 2.
- iv. The doctor who headed the clinical trials was responsible for carrying out the clinical trial from the pharmaceutical company, deciding such matters as the time period for the trial, the number of subjects, the method for administering new products, the characteristics to be inspected, the criteria for effectiveness and side effects, creating the clinical trial plan (protocol), and furthermore, had responsibility for determining which medical facilities and doctors would participate, collecting the results of the data, and finalizing the research papers.
  - v. In order to participate in the clinical trial, tests on toxicity and medicinal effect had to be completed in pre-trial studies. For the pre-trial studies, there were physiochemical trials related to the chemical makeup, quality, and characteristics of the product, and animal testing to evaluate toxicity, medicinal effect, absorption, and excretion, among other things.
  - vi. The U.S. Center for Disease Control, in July 1982, reported on cases of hemophiliac patients, who, without another underlying disease, had cellular immune deficiency and developed pneumocystis carinii pneumonia—thereafter, identified as AIDS. The U.S. Hemophilia Foundation, on December 21 of that year, reported an increasing number of cases of hemophiliacs with AIDS. The American parent company of L (“Western L”) obtained manufacturing approval for heated blood production on March 21, 1983. On March 24, the U.S. Department of Health and Safety welcomed approval of the heated product, and stated they hoped this product would provide protection against AIDS for hemophiliacs. From May 16-19, 1983, at the 22nd “Blood Transfusion and Immunohematology Specialists Committee” convention in Lisbon, the committee decided AIDS could be transmitted by means of blood and blood products, and recommended counter-measures. In Japan, the Ministry of Health and Welfare (at that time, the name of both the offices and the services), Pharmaceutical Affairs Bureau, Biologics and Antibiotics Division section chief C (“Section Chief C”) learned that hemophiliacs were getting AIDS in the United States, which created a momentum in June of 1983 for the establishment of an AIDS research group in Japan to investigate the AIDS outbreak and the pharmaceutical production of

blood clotting products to combat AIDS, and appellee assumed leadership of this group. That August, at the third AIDS research conference, a blood products subcommittee was established to consider blood product counter-measures.

- vii. In May 1984, the D doctors group confirmed that human immunodeficiency virus ("HIV") is the origin of AIDS, and therefore recognized that HIV causes AIDS.

**(4) The sequence of events until there was manufacturing approval for heated blood product in Japan**

- i. In August 1983, P held 51.1%, or approximately half, of the market share in Japan for unheated formula, while Q held 16.6%, L held 11.3%, M held 8.4%, O held 8.4%, and R held 4.2%.
- ii. In 1981, N obtained permission from West Germany to sell heated blood products. Western L, as described above, had obtained manufacturing approval from the United States on March 21, 1983, and was selling heated blood product. O developed the heated blood product in 1982. P, on August 30, 1983, delivered to the appellee samples of heated blood product developed from three types of heating methods, and even though an evaluation was requested, at that time appellee did not settle on a heating method, conduct clinical trials, or develop a practical use from these samples.
- iii. On September 14, 1983, at the first blood products subcommittee meeting, the committee reached the conclusion that a trial for the heated blood products was more necessary for hepatitis than for AIDS, and decided to carry out such a trial. In September 1983, the appellee indicated to P he would hand in the sample by October 8, while P, on October 7, requested the hand-in to be postponed until October 20. However, P did not hand in the sample by the twentieth of the same month. On November 10, 1983, the Pharmaceutical Affair Bureau, Biologics and Antibiotics Division held a meeting for the seven pharmaceutical companies that had applied for manufacturing approval for the heated blood product treatment. At this meeting, the Secretary of the Ministry of Health and Welfare explained that in the clinical trials:

1. the number of cases in the clinical trials, in at least two institutions, was to be more than 20 cases, for a total of more than 40 cases;
2. the dosing period was to be for three months, and records kept for two to three months; and
3. Test 1 could be omitted.

The appellee, on December 13, 1983, had a meeting with the seven pharmaceutical companies where a plan was drafted for the clinical trials:

1. For Test 1, they would conduct heated blood product trials, and start work on Test 2 in March 1984.
2. For Test 2, a nation-wide committee on the treatment of hemophiliacs would be created, and thereupon each company's clinical trials would be lumped together as a multi-center trial.
3. The application for manufacturing approval would be consolidated.
4. The interval for the clinical trial would be one year, and the number of cases for the trial at each center would be at least 40.

By the end of 1983, appellee received his commission from the seven pharmaceutical companies and became the head doctor for the trials. Section Chief C, around the end of 1983, received a protest from an employee of a foreign pharmaceutical production company about a request from appellee for a donation.

In the beginning of January 1984, Section Chief C spoke with Dr. E, the Chairman of the blood products subcommittee, and committee members Dr. F ("Dr. F") and Dr. G ("Dr. G"), about the impossibility of uniformity in the clinical trials, the necessity of Test 1, and rumors concerning the appellee—that appellee was raising funds through the foundation he had established, S ("S"), and conducting clinical trials. Drs. F and G, on January 12, 1984, shared with the appellee what they had heard from Section Chief C. Because of this conversation, on January 17, 1984, appellee informed the pharmaceutical companies by letter or by phone of his wish to resign as the leading doctor of the clinical study. The appellee again received the commission from each of the pharmaceutical companies, and in March 1984, once again became head doctor of the clinical trials. After the appellee was reinstated as head doctor, he started work according to plan for Test 2. Test 2 for the heated blood product

was completed, the manufacturing approval application was written in April and May of 1985, and as discussed below in part 2.(7).iv, five of the pharmaceutical companies were given approval on July 1, 1985.

**(5) On contributions to S**

- i. S received ¥10,000,000<sup>23</sup> from M on May 25, 1983, ¥10,000,000 from L on May 31, ¥10,000,000 from Q on June 15, ¥3,000,000<sup>24</sup> from O on July 7, and ¥10,000,000 from P on July 13, but the money was put in a bank account under the name “Representative A of Foundation S.” In November 1984, appellee sponsored the 4<sup>th</sup> International Symposium on Treatment for Hemophiliacs with over ¥25,500,000<sup>25</sup> from the seven pharmaceutical companies, and put the surplus of ¥10,000,000 in the “Representative A of Foundation S” bank account.

**(6) On the appellee’s statements**

- i. On July 16, 1985, a hemophiliac infected with HIV, H (“H”), visited O’s Tokyo office, and said, “as you specialize in vaccines, and possess heating technology, it would be relatively easy for you to make heated blood coagulation factor, and I can’t wait for it to be available to everyone as soon as possible.” and “P is late in developing the heated blood product, so it will take too much time to collaborate with them.” On August 15, 1985, regarding the heated blood product, H told appellee that “L said they could get it out faster” and appellee stated, “if only one company comes out with it, then it will cause a scramble for the formula, which is a problem. That’s why we made all the companies wait until all the companies were prepared. Otherwise, everybody will have problems.”
- ii. On January 19, 1988, appellee gave the interview to the Mainichi Shinbun as recorded in Attachment 2.
- iii. On March 8, 1994, appellant, before writing the magazine article and book at issue in this case conducted an interview with the appellee. The contents of this interview are recorded in Attachment 3.

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<sup>23</sup> *Translator’s Note:* Approximately US\$ 109,709.24 at current exchange rates.

<sup>24</sup> *Translator’s Note:* Approximately US\$ 32,912.77 at current exchange rates.

<sup>25</sup> *Translator’s Note:* Approximately US\$ 279,758.55 at current exchange rates.



**(7) Appellant's writing process**

- i. Appellant, in the last part of March 1992, read the work of a freelance journalist entitled "The AIDS Accusation." The article stated that that the heated blood product was sold in the United States in 1983, and that P, which held the largest market share in unheated blood product, was late in developing the heated blood product, and that if the heated blood product had been introduced earlier, P would have been in danger of losing market share, so P's development period was "adjusted." The article also stated that, as a result of the "adjustment," appellee was delayed in conducting the heated blood product trials, and that appellee received funding from P, L, O, and M via S.
- ii. From the beginning of May 1992, appellant attended the litigation in Tokyo district court ("Tokyo HIV Case") brought by hemophiliacs in order to obtain monetary compensation from the government and the pharmaceutical companies for HIV infection from unheated blood product, and obtained and read the complaint, evidentiary documents, and witness examination transcripts from that trial. According to the Tokyo HIV Case defendant L's brief, dated October 29, 1990, on March 21, 1983, Western L received heated blood product manufacturing approval from the United States. Also, according to defendant P's brief dated October 29, 1990, P completed preclinical quality tests, general pharmacological tests, acute toxicity tests, and the like, in January 1984.
- iii. Appellant learned through the Tokyo HIV Case defense counsel that in December 1983, appellee gathered the pharmaceutical companies for a clinical trial briefing meeting, after which the appellee suddenly resigned as the head clinical trial doctor in January 1984.
- iv. The appellant, before writing the magazine article at issue in this case, read the House of Representatives Budget Committee minutes from February 23, 1988. The minutes revealed that the Pharmaceutical Affairs Bureau Minister had responded that appellee was the "Representative Agent" of L, M, N, O, and P in their clinical trials for the heated blood product, that the five pharmaceutical companies' heated product applications had all been approved for production on July 1, 1985, and that the heated blood product clinical started in

February 1984 for L, March 1984 for M and N, in May 1984 for O, and lastly, in June 1984 for P.

- v. Appellant, on December 25, 1992, interviewed Section Chief C, and learned from Section Chief C that he had been concerned about the delayed start for the heated blood product clinical trials, and that because he had heard rumors about the appellee raising funds, he informed the appellee of these concerns through someone.
- vi. On March 15, 1993, appellant heard the examination of Section Chief C at the Tokyo HIV Case. Section Chief C testified that, at the November 1983 Ministry of Health and Welfare meeting, the Ministry articulated that if Test 1 was unnecessary then heated blood product testing would be easy to do.
- vii. In August 1993, appellant interviewed J who was R's Executive Director, and learned that appellee was intimate with P, and that in relation to the heated blood product clinical trials, appellee was attentive to P's situation, and so probably insisted on performing Test 1 for the clinical trials, and on an extended time period, because P was slow in developing the heated product in comparison to other companies, and that Section Chief C was critical that appellee was gathering funds for S.
- viii. On January 27 and February 4, 1994, appellant interviewed Dr. F. She learned that, Section Chief C asked Dr. F to speak to appellee about the rumors S that was receiving funding for the clinical trials from the pharmaceutical companies. Appellee responded, "it's already over," but did not state that he was no longer requesting contributions.
- ix. After September 4, 1993, appellant collected detailed information from persons involved at K University, and saw stacks of bankbooks more than ten centimeters thick lying about on the shelves in front of the desk in the appellee's office.
- x. Before writing the magazine article at issue in this case, appellant read U's newsletter "All Friends No. 20." The speeches appellee had given at the national convention on August 14, 1983, were published in the newsletter, and according to his speeches, he said concerning S: "I am now collecting money. Currently, we have

gathered more than ¥80,000,000<sup>26</sup> thanks to the assistance of the friends of the university.”

- xi. Before writing the magazine article at issue in this case, appellant heard from H about H’s visit to O’s Tokyo office and the conversation he had with appellee (See Part 2.(6).i).
- xii. Before writing the magazine article at issue in this case, appellant obtained and read the transcript of the interview T newspaper had with appellee. (See Part 2.(6).ii).
- xiii. Before writing the magazine article at issue in this case, appellant interviewed appellee, as mentioned in Part 2.(6).iii.

**(8) On the appellee’s decline in social standing caused by the statements in this case<sup>27</sup>**

- i. About Statement 1:  
Excluding the last sentence of statement 1, (“In actuality, is there anything besides Dr. A’s greed that explains why there are so many patients who did not necessarily need to be infected with AIDS?”), statement 1 is grounded in fact that after November 1983, appellee met with P (the largest producer of blood products and the last to develop the heated blood product in Japan), delayed the clinical trials for the heated blood product, and as a result, manufacturing approval was not obtained in Japan until July 1985 (four months two years later than in the United States), and that such facts lower appellee’s standing in society. The last sentence in statement 1 is based on [appellant’s statement of] facts that appellee delayed the heated blood product clinical trials, and [appellant’s statements of] facts in statement 2. Appellant’s assertion—that it was nothing more than appellee’s greed in promoting P’s interests—is an opinion or commentary that lowers appellee’s standing in society.
- ii. About Statement 2:  
In statement 2, it is stated as fact that appellee solicited contributions from all the pharmaceutical companies for S during the heated blood

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<sup>26</sup> *Translator’s Note:* Approximately US\$ 877,673.90 at current exchange rates.

<sup>27</sup> *Translator’s Note:* These statements can be found in Attachment 1.

product clinical trials. Read together with statement 1, appellee loses standing in society because it is stated that the reason appellee delayed the trials to promote P's interests was to gather money for S during the time of the heated blood product clinical trials.

iii. About Statement 3:

Excluding the last sentence statement 3 ("Other people guessed that the large sum of money was contributed not just because of S, but because of Dr. A's status in the scientific community), statement 3 states as fact that appellee, during the time of the heated product trials, solicited funds from all the pharmaceutical companies for S corporation, and that utilizing his superior position as the head doctor of the trials to levy contributions would be very problematic, is an opinion or commentary that lowers appellee's standing in society. Also, the last sentence of statement 3 lowers appellee's standing in society.

iv. About Statement 4:

In statement 4, along with stating as fact that appellee delayed the clinical trials in order to retard manufacturing approval for the heated product because he received donations from all the pharmaceutical companies, appellant stated that, on this basis, the appellee sold his soul as a doctor for money—an impermissible act for a doctor. This is an opinion or commentary that lowers appellee's standing in society.

v. This case is related to the public interest, and moreover, the purpose is mainly to serve the public good.

3. The high court ruled on the truth of the facts as follows. The high court approved payment of appellee's request for ¥4,000,000<sup>28</sup> in damages, with interest, but denied the remaining claims.

(1) The assertions in statement 1 that P's start date for the heated blood product clinical trials was delayed in November 1983, and the delay was due to a meeting P had with the appellee cannot be proved as true. The assertions in statement 2 the solicitation of donations from the pharmaceutical companies to S corporation during the heated blood

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<sup>28</sup> *Translator's Note:* Approximately US\$ 43,883.69 at current exchange rates.

product clinical trials cannot be proved as true. Therefore, the last sentence of statement 1 is an opinion or commentary based on the facts that cannot be proved as true. The assertions in statement 3 that solicitation of donations from the pharmaceutical companies to S corporation during the heated product clinical trials cannot be proved as true, and the statement that appellee used his superior position as the head doctor of the trials to levy contributions would be very problematic, is a opinion or commentary which is based on facts that cannot be proven as true. The last sentence of statement 3 cannot be proved as true. Since the assertions in statement 4 that because the appellee received donations from all the pharmaceutical companies, he delayed the clinical trials in order to delay manufacturing approval for the heated blood product cannot be proved as true, the statement "How much money was he stained with for him to sell his soul as a doctor?" is an opinion or commentary based on facts that cannot be proved as true.

(2) Although there is adequate cause regarding appellant's belief that P delayed the clinical trial for a period of time, there is no adequate cause to believe that appellee delayed the clinical trials for P, and that appellee solicited funds from pharmaceutical companies during the clinical trials, and therefore appellant is not able to show adequate cause so that her assertions are believed to be true.

(3) Therefore, it is possible to recognize the tort of defamation in this case.

4. However, we are unable to affirm the high court's judgment. The reasons are as follows.

(1) It is not illegal to assert facts that cause injury to reputation if they can, in significant part, be proved as true, as long as the asserted facts are related to the public interest, and moreover, if the purpose in asserting the facts was mainly to serve to public good. Even when there is no such proof, the intent or negligence is negated if there is adequate cause for the actor to believe that the asserted facts, in significant part, are true (citing 1962 (O) No. 815, judgment of the First Petty Bench of the Supreme Court of June 23, 1966, *Minshū* vol. 20, no. 5, p. 1118; 1981 (O) No. 25, judgment of the First Petty Bench of the Supreme Court of Oct. 20, 1983,

Saibanshū Minji no. 140, p. 177).<sup>29</sup> And unless the opinion or commentary amounts to a personal attack, it should not be illegal to state an opinion or commentary that causes injury to reputation, if it is based on facts that can be, in significant part, proved as true, if it is related to the public interest, and moreover, that it was stated mainly with the purpose of serving the public good. Even when there is no such proof, the intent or negligence is negated if there is adequate cause for the actor to believe that the asserted facts, in significant part, are true (citing 1985 (O) No. 1274, judgment of the First Petty Bench of the Supreme Court of Dec. 21, 1989, Minshū vol. 43, no. 12, p. 2252; 1994 (O) No. 978, judgment of the Third Petty Bench of the Supreme Court of Sept. 9, 1997, Minshū vol. 51, no. 8, p. 3804).<sup>30</sup> Here, even though the truth of the facts denoted in record and the facts the opinion or commentary is based on cannot be proved, as described below, the appellant is able to show there was adequate cause to believe the truth of the facts, and therefore the intent and fault is negated, and the act should not amount to the tort of defamation.

## (2) On Statements 1 and 2

- i. According to the facts above, appellee said to H that if only one company produced the heated blood product, because of the problem of a fight over pharmaceutical production, they preferred to wait until all the companies that hitherto were able to produce the heated blood product were ready. In the interview with T newspaper, on the development of the heated product, appellee stated L was leading, P was late, and in order to make a safe product, the advance of the clinical trials was “adjusted,” so all the companies could compete equally, and it was clear to appellee that L was first and P was late in the heated blood product development, and that appellee delayed the clinical trials for P. According to the facts above, the appellant, before writing the magazine article, knew about what the appellee said, and also, when the appellant interviewed the appellee before the magazine article and book, it was clear that P’s heated blood product development was delayed, and that appellee delayed the clinical

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<sup>29</sup> *Translator’s Note*: Fujito v. Yomiuri Shimbun, 20 MINSHŪ 1118 (Sup. Ct., June 23, 1966); Jūzenkai Hospital v. Enomoto, 140 SAIBANSHŪ MINJI 177 (Sup. Ct., Oct. 20, 1983).

<sup>30</sup> *Translator’s Note*: Ebihara v. Katsuma, 43 MINSHŪ 2252 (Sup. Ct., Dec. 21, 1989); Kōno v. Sankei Shimbun, 51 MINSHŪ 3804 (Sup. Ct., Sept. 9, 1997).

trials. According to the facts above, the appellant, through the data she collected, clearly learned that Western L received manufacturing approval from the United States on March 21, 1983, that P completed quality, general pharmaceutical, acute toxicity, and other tests in January 1984, and that P was the last to begin as L, M, N, O, and P were commencing heated blood product clinical trials. The facts concerning the development of the heated product—that L was leading, and P was late—can be substantiated by appellee's statements. According to the above, through her research, appellant clearly learned that, although the Ministry of Health and Welfare determined Test 1 was unnecessary in November 1983, appellee nonetheless persisted in performing Test 1, that P was extremely late in comparison to the other pharmaceutical companies in developing the heated blood product, and in consideration of P, appellee took a long time doing the clinical trials, and that L, M, N, O, and P all received manufacturing approval on July 1, 1985. These facts, that appellee met with P and delayed the heated product clinical trials, can be substantiated by appellee's statements. According to the above, at the time of the writings at issue in this case, there is adequate cause to believe in the truth of the facts appellant asserted in 1.1—namely, that appellee met with P in or after November 1983, which was late in developing the heated product and held the largest market share of blood products in Japan; that the heated product clinical trials were delayed; and as a result, manufacturing of the heated blood product was not approved until July 1985 in Japan, more than two years and four months later than in the United States.

- ii. Looking at statement 2 in combination with statement 1, for the part in statement 2 that indicates appellee delayed the clinical trials because he received contributions from the pharmaceutical companies through S corporation, “the period of the clinical trials” is not limited to the time the clinical trials were actually conducted, but can be more expansively understood to encompass the period when the clinical trials were taking shape. According to the facts above, the appellant clearly learned through her investigation that, concerning S Corporation, appellee said on August 14, 1983, “I am now collecting money. Currently, I have gathered more than ¥80,000,000,<sup>31</sup> thanks to the assistance of all our good friends;” that

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<sup>31</sup> *Translator's Note:* Approximately US\$ 877,673.90 at current exchange rates.

Section Chief C, as he had heard a rumor that appellee was collecting money in relation to the clinical trials, asked Dr. F to tell the appellee about the rumor; that Dr. F told appellee that a rumor was being circulated that he requested money from the pharmaceutical companies for the clinical trials to be sent to S, and appellee answered, "That's already over," but did not state he was not asking for money. According to the above, at the time of the writing, there was adequate cause to believe the truth of the facts asserted by the appellant in statement 2; namely, that appellee collected funds from the pharmaceutical companies during the time of the heated product clinical trials through S corporation.

- iii. Based on the above facts, the last sentence of the opinion or commentary of statement 1 ("In actuality, isn't the reason why there are so many patients living with HIV who did not necessarily need to be infected, after all, nothing more than Dr. A's greed?") cannot be said to be outside the scope of an opinion or commentary.
- iv. Therefore, statements 1 and 2 should not establish the tort of defamation.

### **(3) On Statement 3**

- i. As stated above, at the time of the writing, there was adequate cause to believe the truth of the facts asserted by appellant that appellee gathered contributions from pharmaceutical companies for S. And, according to the facts above, it is clear appellee became the AIDS research group leader in June 1983, that in September, the research group established a blood products subcommittee to create a plan for heated product clinical trials, and by the end of December, the appellee became the head doctor of the multi-center clinical trials. Therefore, the statement based on the facts above (that appellee utilizing his superior position as the head doctor of the trials to levy contributions would be very problematic) is not outside the scope of an opinion or commentary. Also, concerning the last sentence of statement 3 ("Other people guessed that the large sum of money was contributed not just because of S, but because of Dr. A's status in the scientific community."), there was adequate cause to believe the truth of the statement at the time of writing. According to the facts above, from the interview with T newspaper, it has been acknowledged that



appellee held multiple symposiums, and that the money that was contributed came from pharmaceutical companies. Because the amount of money and the status of the appellee in the scientific community were plainly tied, there was adequate cause to believe the truth of the last sentence at the time of the writing. Therefore, statement 3 cannot amount to the tort of defamation.

**(4) On Statement 4**

- i. As stated above, at the time of the writing, there was adequate cause to believe the truth of the facts appellant asserted (that appellee received contributions from the pharmaceutical companies at the time of the trial, and delayed the clinical trials for the manufacturers left behind during the manufacturing approval process for heated blood product). Also, according to the above, appellant knew through her research that Section Chief C, as he had heard a rumor that appellee was collecting money in relation to the clinical trials, had asked Dr. F to tell appellee about the rumor; that when Dr. F told appellee that a rumor was being circulated that he was soliciting money for S from the pharmaceutical companies participating in the clinical trials, appellee answered, "That's already over," and did not state he was no longer asking for money. According to the above, at the time of the writing, there was adequate cause to believe the truth of the facts that appellee received money from the pharmaceutical companies, and appellee delayed the clinical trials for the companies being left behind in the manufacturing approval process for the heated blood product. As to the statement, "how much money was he stained with for him to sell his soul as a doctor?" it is based on these facts, and it cannot be said to exceed the scope of opinion or commentary. Therefore, statement 4 cannot be said to amount to the tort of defamation.

5. Therefore, recognizing the tort of defamation in this case, as partially affirmed in the high court's judgment for the appellee's claim, clearly violates the law. For this reason, we have no choice but to dismiss the part of the judgment in which appellant lost her case. And, as appellee has no basis for his claim, and because the rejected district court decision was correct, the appellee's appeal should be rejected. This is our unanimous judgment.

(Presiding Justices Saiguchi Chiharu, Izumi Tokuji, and Shimada Nirō)

**(Attachment 1)**

Statement 1. Nevertheless, why did Dr. A delay the start of the clinical trials? The Ministry of Health and Welfare held a meeting to discuss the clinical trials in November of 1983. That is eight months after the United States authorized the clinical trials in March 1983. After Dr. A met with the late-starting P, the start date for all the clinical trials were further delayed, until they finally began in February 1984. As Dr. A stated in his February 4, 1988, interview with T newspaper, “P was quite late. (On the other hand), L had done it quite a bit earlier. Therefore, it follows there is a difference,” and furthermore, “we were in charge of the clinical trials. It’s because the others hurried through that it meant I made a few adjustments.” As a result of “adjusting” the clinical trials for P, which, with 40%, has the largest share of the blood products market, the heated blood product was not licensed in Japan until July 1985. In actuality, is there anything besides Dr. A’s greed that explains why there are so many patients living with HIV who did not necessarily need to be infected with AIDS?

Statement 2. At the time of the clinical trials, it is known Dr. A solicited contributions from the pharmaceutical companies. Dr. A, as chairman of the board, had the money donated to S corporation.

Statement 3. Did Dr. A receive this type of financial sponsorship? As one who has seen the countless bankbook confirmations, it seems Dr. A continuously received funds. Dr. A, as the responsible party and representative of the clinical trials, was absolutely in a superior position in relation to the pharmaceutical companies, and if he abused that position to levy contributions, it would be a large problem. Other people guessed that the large sum of money was contributed not just for S, but also to protect Dr. A’s status in the scientific community.

Statement 4. Because he received financial sponsorship, Dr. A delayed the clinical trials so that no company would fall behind: how much money was he stained with for him to sell his soul as a doctor?

**(Attachment 2)**<sup>32</sup>

Reporter: Doctor, for example, the timing of the heating treatment has been delayed two years and four months, right?

Appellee: No, well regarding this, I naturally had a connection. Even now, well, if I am still connected to hemophilia . . .

Reporter: Doctor, all the clinical trials . . .

Appellee: . . . were done by me. (omission) If we are going to speak on why we did it, we thought a small, quality group of people would be good. And then, there could not be any harm. If it was the same, and if it was the same people, I would do it again. If you want to do it, you should do it. And you cannot afford to create any harm. Therefore, I wanted to show there would be no harm. I wanted to prove it. That's how I did it. That is to say, I could not bear to turn my patients into guinea pigs. (omission) Well, then Phase 1 was omitted.

Reporter: But to do that means leaving patients in the cold, right?

Appellee: That's what Mr. C said to do. And then, of course I was in a very tight place. Very. Then F came to me and reported that Mr. C had said, "Aren't you doing this in order to solicit money?" But, I don't solicit money. That's why I left. At once. I said, "You, you do it for me. I don't want to know." That was only for one month. But this was not the Ministry of Health and Welfare's responsibility. To the patients, I have the underlying spirit of a doctor. But actually, at that time, I was only doing the clinical trials. I was only doing the clinical trial, but officially, they wanted to do it concurrently with Test 1. And, they were done concurrently . . .

Reporter: Doctor, only P was late in their application . . .

Appellee: Yes, yes, but that came after. P was quite late. P was late, but well, L had a head-start.

Reporter: They had already done it in America.

Appellee: They did it earlier, so it follows there was already a difference.

Reporter: Naturally, there is a difference.

Appellee: Yes, there is. (omission) If you were to ask me why this is, then certainly the person who does it earlier, will naturally do it faster. They started the clinical trials first, so they were able to do it earlier. However, I have had quite a bit of experience on investigational committees. Having done this, I know that when only one company suddenly comes out and makes an application, the investigation committee makes adjustments.

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<sup>32</sup> *Translator's Note:* This attachment includes portions of Dr. Abe's interview given to the MAINICHI SHINBUN on Jan. 19, 1988.

Saying that, approving only one company is usually not what we want. As few as two or three companies do it together. Even if we were very much separated, I was the one doing the clinical trials. It's because the others did it quickly. Therefore, it meant I made a few adjustments. That's what it means. Of course, if you want patients to use it with peace of mind, you can't give any old product as it invariably creates trouble afterwards. Yes, that's how, I've done it time and time again. (omission)

Reporter: Well Doctor, and the financing help, for the symposium . . . (omission)

Appellee: Well, after the third symposium we decided that not only P, but that all would contribute equally . . .

Reporter: So, on the amount of the proceeds . . .

Appellee: I don't know anything about the amount of the proceeds. However, to a certain extent, if I heard "our portion is too much" then I would say "really?" Anyway, I would add, "we only need this much." So, as to the remainder, because there's no need to have any money left over, that remainder would go to everybody . . . that's the way I have always responded. Therefore, as much as possible, it is not about how one company falls behind, or another company goes bankrupt—I want everyone to compete on the same level.

**(Attachment 3)**<sup>33</sup>

Appellee: F and I have slightly different opinions. That is, F, earlier in your questions, and this was a little—well, it was not the best. There is an issue, that I, huh, delayed the trials. And the clinical trials I did were vitally important. That's where you are mistaken. That is, it must be proved that the product is effective. And then, that there are no side effects. Before the product can be effective, it must be proved that the conditions are good. Then, it must be proved there are no side effects. Right. Then, in my opinion, I thought that you can get the "green light" quickly. I think that you already understand this from our previous conversation, but in your writings, you only emphasize that I delayed the trials.

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<sup>33</sup> *Translator's Note:* In this interview conducted with Yoshiko Sakurai on March 18, 1994, shortly before the publication of the magazine article and book at issue, Dr. Abe reiterates the need to conduct clinical trials thoroughly and methodically in order to create quality treatments. He argues against the use of the word "delay" to explain the schedule of the clinical trials because the original schedule maximized the chance of government approval of the resulting treatment without requiring further time-consuming clinical trials. In addition, Dr. Abe argues that he made every effort to work as quickly as possible. Dr. Abe also tells Sakurai he believes her writings oversimplified the issue, and did not give readers the full picture or explain the efforts he made.

Appellant: Doctor, some time ago, you said yourself you delayed the clinical trial.

Appellee: No. I said I delayed it, but this is a mistake. I wish to retract this. (omission)

Appellant: Well, P had fallen the most behind in the clinical trials, right?

Appellee: Ah, P, well, because the Japanese people were hopeless, they were told to help America's V company. That is to say, until then, V's product was used with P's name. We did that in order to get early permission, are you following me, to use a product on patients before it is heated, and the same product that is heated, to compare that . . . well it's a shortcut. And then those who used L first, are you following me, but now others, like the P company which uses V's product, to do it, and then M . . . . When you don't use a method like this, you do an analysis of the components and such, and then you have to do a double blind study. This takes time. So I went and said how long should we wait and I was told about month, so, for hemophilia, I said let's let L go first. And after that, we did them one by one.