

Pax Moot 2021 Von Mehren Round – Facts

Claimants: A group of citizens from Hira led by Ms Li

Defendants: Global Medical Inc., a pharmaceutical company

1. Global Medical is a pharmaceutical company incorporated in Delaware in the US but its management is done mainly from Belgium. It joined the global race towards developing a vaccine against the SARS-CoV-2 virus. The company received grants from the Belgian State, the US federal government and the European Union in order to facilitate and speed up their research.
2. The final testing of a vaccine, namely the testing on humans, usually takes place in three phases. For all three phases, pharmaceutical companies rely on volunteers.
3. The first two phases of testing by Global Medical took place with volunteers in Belgium, Hira (a State in Southeast Asia) and in four states in the US (California, Michigan, Ohio and Pennsylvania). On 20 July 2020, the phase one trial showed that the vaccine stimulates antibody response. On 27 July 2020, the phase two trial was launched in a much larger group of people to see if the injection is safe.
4. In October 2020, Global Medical announced that it had begun the third and final phase of the clinical trials. For the trials in Hira it contracted with Vipimo, a local laboratory. Vipimo contracted with volunteers for the testing. Soon after its announcement, an anonymous whistle blower leaked footage and information about the earlier tests in Hira.
5. The person spoke to the media in Hira:
Global Medical is abusing poor people in the southeast Asian State of Hira in order to develop a vaccine for rich countries. They must think that Colonialism has never ended. I am shocked by what I saw. At first Vipimo, the Hiran laboratory contracted by Global Medical, recruited volunteers to participate in its trials. As the recruiting did not run smoothly and as Global Medical wished to speed up the development, Vipimo began making the vaccine available to the general populace under what it called an "experimental treatment programme". This was nothing more than a trial run for the vaccine that was still under development and not yet clinically approved. The participants (which I refuse to call volunteers) were told that if they subscribed to this "experimental treatment" they would probably develop a high rate of immunity and in this way help to save the lives of their elderly and children. The purpose of the programme was in fact to increase the exposure to the vaccine in order to obtain data regarding it.
6. This was subsequently taken over by the media in the US and in Belgium and several other European Countries.
7. A spokesperson of Global Medical reacted saying:
A Staff of the Vipimo Lab is spreading false information about our programme. In so far as anyone takes this person seriously, we would like to emphasize that Vipimo never infringed any law in Hira. The reason why we chose to work with Vipimo is firstly its long-standing reputation as a successful research laboratory in the region and secondly the spread of the virus in Hira. The level of infections there was high and social distancing was difficult as the country has a large informal sector where people work in markets or small shops which are frequently visited by locals, and as people move around mainly in crowded buses or by foot. Giving a trial vaccine to selection groups of people within the hot zones of the virus in order to control its spread is a

decision we took purely for public health concerns and it is a decision we made with the municipal government of Hira.

8. The vaccine Global Medical was developing would, like other vaccines, have made use of squalene, a naturally occurring substance which is found in large quantities in shark liver oil. Even before the pandemic, about 3 million sharks a year were harvested for their livers. Estimates of conservationist groups indicated 500.000 more sharks would be needed to meet COVID-19 demand. These concerns moved Global Medical already in 2019 to start developing a method by which it extracts a small amount of squalene from low-yield sources such as sugar cane and uses a chemical method to develop semi-synthetic squalene that is amplified. Global Medical called this newly developed adjuvant 'Jaws'. Taking into account the concerns of conservationist groups, Global Medical decided to make use of the newly developed semi-synthetic adjuvant immediately, without further separate testing. As Hiran law did not require any approval for the use of the new adjuvant, it is presumed that all Hiran test persons received a vaccine containing the adjuvant 'Jaws'.
9. It turned out that the newly developed semi-synthetic adjuvant used in the vaccine, Jaws, caused a severe allergic reaction in a much larger percentage of patients than initially expected. Hundreds of Hirans suffered from chest cramps and heart palpitations shortly after being injected with the vaccine. They left the laboratory immediately after receiving the injection, being told to simply rest at home and come back a few days later to undergo further tests. Some developed permanent kidney damage or immunodeficiency after their treatment. Moreover, the test results showed that the immunity that people developed after having received the vaccines fades after four to six months. This led to morbidity and increased contaminations.
10. Global Medical worked further on the vaccine, ceased the use of the adjuvant 'Jaws' and started using 100% natural squalene for further trials.
11. In January 2021 full results from the phase three trials indicated that nine out of ten people given the vaccine were protected by it, which was deemed a significant success, and it was approved in Europe and the US. The medical board of Hira also approved the vaccine.
12. At the end of January 2021 the Hiran authorities proceeded to order 10 million vaccines from Global Medical.
13. Global Medical responded, however, that it would only be able to deliver the order a year later. This was because the US and the European authorities had pre-ordered a huge amount of vaccines and Global Medical did not have the capacity to make the vaccine units that fast. The Hiran medical board then requested Global Medical to make the formula available, so that the vaccine can be produced locally. Global Medical responded that the formula is protected by patents registered in all EU countries, in the US and in Hira.
14. It later emerged that the whistle blower was Ms. Li, the head of the laboratory of Vipimo (how this emerged is not known). Ms. Li was fired in August 2020 from her post after openly questioning the use of the semi-synthetic adjuvant Jaws in front of the representatives of Global Medical. After her dismissal she took up a job at a pharmacy. From this position she focused on informing the citizens of Hira about the virus and the dangers of the vaccines in development.

15. As former head of the Vipimo laboratory, Ms. Li knew a part of the formula and managed to steal the rest of it. She started ordering the ingredients of the vaccine. With the approval of the Hiran government, which she expects to receive, she will be able to produce the vaccine in Hira on an industrial scale from May 2021 and sell it at cost price.
16. Together with some Californian volunteers, who participated in phase one and two of the clinical trials and fear that they also were injected with a vaccine containing the Jaws adjuvant, various Hiran citizens who had been ill and suffered loss of income or whose family members had died, instituted collective proceedings for damages against Global Medical in California under the leadership of Ms Li. The class action procedure was initiated on 14 February 2021. Willy, a whale shark, represented by Shark Allies, a Conservationist group, requests to be joined as an interested party to the proceedings: he fears that litigation concerning synthetic products would only serve to increase the harvest of squalene from shark livers. The court in California has not yet decided on jurisdiction and has not yet certified the class action.
17. In March 2021 some of the Hiran participants and researchers including Ms. Li sue Global Medical for damages in Belgium. Their claim is based on the inadequate information they (as researchers and participants) received, the physical harm the participants suffered, and the high number of injuries caused by the vaccine testing, something which affected the entire community.
18. Global Medical brings counterclaims in Belgium against Ms. Li for a court injunction to prevent her from selling the vaccine of which it holds the patents.

* *
*

Claimants: you represent the Hiran participants and Ms Li in the claim before the court of first instance of Antwerp, Belgium.

Defendant: you represent Global Medical before the court of first instance of Antwerp.

Assuming that both the EU and Hira are Contracting States to the 2019 Hague Judgments Convention and that it has entered into force, each party should address the court on:

- 1. the relevance of the parallel class action in California to the Belgian proceedings (the court is not interested in challenges to jurisdiction on other grounds)**
 - 2. the law that the Antwerp court should apply, if it accepts jurisdiction, to the various issues raised by the claimants and defendants; and**
 - 3. the enforceability of the ensuing Belgian judgment in Hira**
-