

On 20 August 2007, in Frazer v. Schlegel, the United States Court of Appeals for the Federal Circuit decided that researchers Ian Frazer [5] and Jian Zhou owned the rights to the vaccine patent for Human Papillomavirus, or HPV, instead of a research team led by Richard Schlegel. Frazer v. Schlegel reversed the decision that the Board of Patent Appeals and Interferences had previously made, awarding the patent to Schlegel on the basis that Frazer’s patent application contained inaccurate science. However, once appealed, the Federal Circuit judges found Frazer’s science to be accurate, granting him rights to the vaccine patent. In 2006, the US Food and Drug Administration [6], or FDA, approved the first HPV vaccine, which has since been effective in protecting women from cervical cancer by up to ninety-seven percent if they were vaccinated before contracting HPV. The Circuit’s decision gave Frazer ownership of the patent for the HPV vaccine, which physicians have administered over 120 million doses of to people in the US.

In the US as of 2021, HPV is the most common sexually transmitted infection, or infection passed along from person to person during sexual encounters. Both men and women can contract and spread HPV. The Centers for Disease Control and Prevention, or CDC, estimated that forty-three million adults were living with HPV in 2018, and that almost every sexually active person will get HPV in their lifetime if they are not vaccinated. Most often, HPV appears with no symptoms. However, it may also appear as a form of genital warts in both sexes. During research he conducted in the early 1980s, German scientist Harald zur Hausen discovered that HPV caused cervical cancer in women. Since then, HPV has also been discovered to be associated with causing other cancers, such as anal and vaginal cancers. As of 2021, the CDC estimates that over forty-three thousand people each year contract HPV-associated cancer, most commonly cervical cancer in women. Scientists around the world began working to develop a vaccine to prevent men and women from contracting HPV and contracting HPV-associated cancers in the early 1990s.

Debates around the rights to the HPV vaccine were largely focused on which team of scientists was the first to understand how to develop Virus-Like Particles, or VLPs, to create the HPV vaccine. VLPs are organic structures that mimic a virus’s shape and protein structure but lack the viral DNA that makes viruses infectious. Scientists can use VLPs in vaccines to trick the body into initiating an immune response without actually making the person sick. An immune response is a body’s way of defending itself from foreign particles like viruses or bacteria. After the body launches an immune response against a specific type of foreign particle, it will remember the particle, or build immunity against it, which allows the body to get rid of the foreign particle faster if it encounters the particle again in the future. Thus, because VLPs resemble a virus, making vaccines with VLPs helps the body build immunity against a virus without actually having to be infected. HPV vaccines use VLPs that resemble HPV so the body can build immunity against that virus.

Scientists can use two major proteins to produce the VLPs for the HPV vaccine, the L1 and L2 proteins. L1 and L2 are proteins that naturally appear on the outer shell of HPV particles. Scientists learned to harvest and use those proteins to create VLPs that are safe for humans [7], as L1 and L2 proteins themselves do not carry HPV DNA that can make a person sick. In the 1990s, scientists discovered that making a VLP with those proteins could help the human body build immunity against HPV. That is because if the body’s immune system recognizes L1 and L2 proteins, it will attack HPV particles, since they have L1 and L2 on their outer surface. When Frazer’s team first filed a patent for the HPV vaccine, they wrote that both L1 and L2 proteins were necessary to make the vaccine. However, shortly after, Schlegel’s team showed that only L1 was necessary.

Frazer’s and Schlegel’s teams each conducted studies that contributed to the production of the HPV vaccine. In 1991, Frazer and his team at the University of Queensland in Queensland, Australia, conducted research that led them to figure out how to construct VLPs for HPV using both the L1 and L2 proteins. They filed an Australian patent for the technology in July of that year. Then, in 1992, Schlegel’s team at the Georgetown University [8] Medical Center in Washington, D.C., conducted research showing that antibodies in mammalian cells could protect the body from HPV infection following exposure to L1 proteins alone. Those findings meant that a vaccine could be constructed using only the L1 protein. Schlegel’s team did not actually produce any VLPs in their study but claimed that their findings provided important background information for producing the vaccine. They filed a US patent application for the HPV VLP technology on 25 June 1992. Soon after, Frazer’s team filed an international patent for the vaccine on 20 July 1992 and a US patent on 19 January 1994. Frazer’s US patent application was placed in interference with Schlegel’s, meaning that both teams were attempting to get the rights to the same technology, so the patent ownership then had to be decided in court.

Judges in previous US court cases had asserted that when scientists file patents in other countries, the United States will recognize it as a US patent as long as the science is accurate, and the scientist filed their foreign patent before their competitors filed any patent. In 1967, the United States Court of Customs and Patent Appeals heard Schur v. Muller. Both Milton Schur and Paul Adolf Muller were inventors who submitted patents for cigarette filters. Muller filed a patent in Switzerland for a cigarette
develop new types of vaccines. Also as of 2021, Schlegel still investigates the science surrounding HPV transmission and works at the University of Queensland that researches different types of cancers and heads a biotechnology company that works to help people.

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On 10 May 2011, the United States Patent and Trademark Office formally granted and published Frazer's patent application. By that point, pharmaceutical companies Merck and GlaxoSmithKline had already licensed the technology from numerous patent applicants. They had been producing and distributing vaccines for people since 2006. As of 2021, Frazer leads a laboratory at the University of Queensland that researches different types of cancers and heads a biotechnology company that works to develop new types of vaccines. Also as of 2021, Schlegel still investigates the science surrounding HPV transmission and works on developing HPV vaccines that can help lower the infection rates in developing countries. According to his staff page at Georgetown University, Schlegel claims to have developed the technology for the HPV vaccine, though the decision made in Frazer v. Schlegel still stands.

**Sources**


