

**Boston University**  
**Journal of Science & Technology Law**

**Legal Updates**

**Updates in Science & Technology Law —  
Biotechnology**

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Cite to this column as: 1 B.U. J. Sci. & Tech. L. 9. Pin cite using the appropriate paragraph number. For example, the first paragraph of this column would be cited as: 1 B.U. J. Sci. & Tech. L. 9 para. 1.

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1. Chiron Corporation of Emeryville, California, ("Chiron") recently won a patent dispute with International Murex Technologies Corporation of Germany ("Murex") over Chiron's patent for a Hepatitis-C screening test. On January 1, 1995, the German Infringement Court ruled that Chiron's patent was valid in Germany and that Murex had to discontinue selling its own tests there. Murex plans to appeal the decision and is seeking to have Chiron's patent invalidated in German Patent Court.
2. Hepatitis-C is a virus that attacks the liver and can cause serious illness or death. Because blood can carry Hepatitis-C, blood banks are required to screen donated blood to prevent infusion related contagion. Both the Chiron and Murex market tests are used worldwide to detect the presence of the virus in donated blood. Murex's test, however, may be more effective than Chiron's. First, it involves different antigens and may detect samples that the Chiron test misses; second, Murex uses a proprietary technology called Sample Addition Monitoring (SAM), designed to eliminate instrument and manual sample dispensing errors that lead to false negative results.
3. Murex points to the overwhelming market response (including a substantial order from the Red Cross) that it received in Germany as evidence of the reliability of its test. It believes that German health authorities feel the Murex test helps protect the safety of the blood supply.

Source: *German Court Rules on Murex-Chiron Patent Dispute*, BIOTECH PATENT NEWS, 1995 WL 8317934 (Jan. 1, 1995).

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4. Chiron Corporation is the subject of another pending lawsuit. Daniel W. Bradley, a medical researcher for the Centers for Disease Control, recently filed suit seeking recognition from Chiron for his contribution to the discovery of the Hepatitis-C virus, as well as damages.
5. Bradley began researching the virus in the 1970s, four years before Chiron formed. In 1975, he and another researcher received the Karl Landsteiner Award of the American Association of Blood Banks and the Robert Koch Prize.
6. Chiron approached Bradley in 1982 with an offer to collaborate on his research, to which Bradley agreed. Then, in 1988, Chiron announced the cloning of the

Hepatitis-C virus, but did not name Dr. Bradley as the coinventor on the patent applications it filed.

7. Before discovery of the virus, it was not possible to develop a blood test to detect it, nor to develop a vaccine to prevent it. The discovery of the virus allowed scientists to develop means of detecting it, and may someday lead to the discovery of a vaccine.
8. Estimates indicate that there are at least 100 million carriers of Hepatitis-C worldwide. The United States tests about 25 million blood donations a year and other developed nations use the test widely as well.
9. Chiron has obtained patents worldwide for its screening test, from which it derives significant revenue. Bradley contends that Chiron never properly recognized nor adequately compensated him for his central role with regard to the blood test. Indeed, he claims Chiron deliberately excluded him as a joint inventor on the Chiron patents.
10. Bradley asks the court to name him as coinventor on the Chiron patents; he also asks that the court invalidate a March 1990 agreement between himself and Chiron, that the court establish a trust to handle the income from the blood test, that he receive royalties and other compensation to which the patent entitles him, and that he receive additional actual and punitive damages. Should Bradley prevail, the patent would entitle the Government, which through Bradley would also be a coowner of the patent, to license the test to other manufacturers.

Source: *Hepatitis C Researcher Sues Chiron*, BIOTECH PATENT NEWS, 1995 WL 8317935 (Jan. 1, 1995).

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11. Genentech, Inc., of San Francisco, California, issued a press release stating that it had agreed to dismiss its pending action against Centocor, Inc., of Malvern, Pennsylvania, for infringement of Genentech's Cabilly patent. Genentech agreed to grant Centocor a nonexclusive royalty-bearing license under Genentech's patents for ReoPro.

Source: *Centocor Confirms Lawsuit Resolution With Genentech*, BIOTECH PATENT NEWS, 1995 WL 8317936 (Jan. 1, 1995).

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12. In Canada, a court exonerated a convicted murderer after DNA fingerprinting revealed his innocence, ending a ten-year ordeal. Guy Paul Morin, 35, had been convicted of raping and murdering his nine-year-old neighbor, Christine Jessop. Jessop disappeared from her home in October 1993 and her body was found 30 miles away in December 1984. Morin was arrested in May 1985.
13. Three initial attempts at typing DNA found in semen samples were unsuccessful, due primarily to the small quantity and poor quality of the semen found on Jessop's panties. The technology available at the time — polymerase chain reaction, or PCR — yielded inconclusive results. But after applying four new techniques to the samples, a team of scientists recently demonstrated Morin's innocence.
14. The scientists had to overcome a build-up of PCR inhibitors in the samples — proteins such as bile pigments, blue jean dyes, or cigarette tar — that prevent the enzymes used to type the DNA from working. To do so, they used four techniques that alone were insufficient, but together were enough to overcome the inhibitors. The four techniques were: dilution of the sample to decrease the concentration of inhibitors and allow the polymerase to interact with the genetic material; increase in the amount of polymerase used; neutralization by bovine serum albumin; and neutralization of sulfur compounds that are a frequent by-product of jeans (and which act as inhibitors).
15. As Morin's defense attorney stated that thanks to the new tests, "DNA has provided an imprint, a fingerprint, so to speak, of the real killer," allowing the court finally to free Morin.

Source: Mara Bovsun, *DNA Test Combo Clears Canadian of Rape-Murder After Ten-Year Ordeal*, BIOTECH. NEWSWATCH, 1995 WL 2196176 (Feb. 6, 1995).

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16. Genentech has formally requested that U.S. Trade Representative Mickey Kantor threaten trade sanctions against Japan for inadequately protecting and enforcing U.S. biotechnology patents.
17. Genentech's President and CEO, Kirk Raab, said that one of the biggest problems American companies face upon entering the Japanese market is "the denial of meaningful patent protection," along with "delays in obtaining approval of

products and in securing issued patents." Specifically, Raab charged that Japan's patent policy allows Japanese biotechnology companies to compete in the market "without incurring the heavy R&D costs carried by U.S. firms."

18. Raab has asked Kantor to list Japan as a "priority foreign country" under the "Special 301" provisions of the Omnibus Trade and Competitiveness Act of 1988. Priority foreign countries are countries that have the most egregious policies denying to Americans adequate intellectual property protection or fair market access. The designation would trigger an investigation into Japan's trade practices and could lead to trade sanctions.
19. A spokesman for the Japanese Ministry of Trade and Industry said this was the first Japan had heard of the problem.

Source: Reginald Rhein, *Japan Patent Policy May Drive U.S. to Trade Sanctions*, BIOTECH. NEWSWATCH, 1995 WL 2196256 (Mar. 6, 1995).