

someone made an improvement that used your patented invention and uses that for commercial purposes—whether they're in a university or not—that is infringement of your patent.”

“We've had correspondence with J&J, but have not resolved the issue,” says NIH patent attorney Thomas Ferris. “We don't consider it infringement [for researchers to use cell lines] as long as it is experimental.” In letters to Dellenbaugh, NIH patent attorneys have said, “[W]e will cooperate in your attempt to enforce your patent rights while at the same time recognizing that the interests of the research programs of the [NIH] must be paramount, if it should

prove to be more practicable to purchase hybridomas from ATCC for research purposes. We suggest that you promote your own sale of hybridomas by publicizing their availability to the NIH research community.”

Dellenbaugh replied that each case should be considered individually, and that a determination should not rest “simply on whether the use is ‘experimental.’ . . . Since [there is] clear economic harm to Ortho, the rationale sometimes used for excepting experimental use from infringement should not apply.”

NIH recently convened a meeting of its internal patent board, a group that

includes patent attorneys and representatives from the various institutes, to consider the policy implications of the letters and has considered making recommendations on these issues to the Department of Health and Human Services. Currently, NIH is telling researchers “to go along the way they are.”

Though Johnson & Johnson is not planning legal action to enforce its patent rights, according to Dellenbaugh, “If we decided an example needs to be made of an egregious infringement, we might do it.” Hence, Ferris says, no matter what policy is laid down, such issues “ultimately can only be resolved in the courts.”—JEFFREY L. FOX

Judge Curbs Use of Toxic Shock Data

In a legal victory for the Procter & Gamble Company, a federal judge in St. Louis last month ruled that the deposition of a researcher at the University of Wisconsin cannot be used in a suit against the company because his research was “preliminary.” The researcher's findings are said to link Procter & Gamble's Rely tampon with the production of toxin associated with toxic shock syndrome.

The ruling is the latest development in a continuing legal battle over the data of microbiologist Merlin S. Bergdoll and its use in court. The controversy has raised questions about access to sensitive research findings during litigation (*Science*, 13 April, p. 132).

The court decision is contrary to an earlier decision by another federal judge, who allowed the data to be discussed in a trial. A Procter & Gamble spokeswoman characterized the St. Louis ruling as a “strong precedent,” while the plaintiff's lead attorney, Tom Riley, remarked that the two decisions “send conflicting signals.” The lawsuit was filed by Michael W. Rogers, whose wife allegedly died of toxic shock syndrome after using Rely tampons in 1980.

Bergdoll, with support from Procter & Gamble and other companies, has studied the production of toxic shock toxin in tampons since 1980. He has not released or published his data because he believes his findings are preliminary and inconclusive. But lawyers for toxic shock victims point out that Bergdoll has discussed his findings with the company and that the company has replicated his findings.

Although Bergdoll and Procter & Gamble have successfully fended off many attempts by lawyers to use the data in court, a U.S. District judge in Fort Worth ruled in 1983 that the data are admissible as evidence. During that trial, Bergdoll's data were revealed for the first time in detail by an expert witness for the plaintiffs, who reported that in laboratory tests Bergdoll found Rely tampons produced more toxic shock toxin than any other brand of tampon.

Bergdoll still contends that his research is incomplete and reiterated this point in a deposition in the Rogers case. U.S. District judge James Meredith agreed with Bergdoll and emphasized the need to protect preliminary research findings in general.

He wrote, “Dr. Bergdoll's research is preliminary in nature; . . . it would be misleading to the jury given the inconclusiveness of its nature. [T]o use [Bergdoll's] deposition in this trial would hinder his research efforts as well as other research efforts at universities throughout the country.” Furthermore, “[A] release of incomplete data will harm Dr. Bergdoll's professional reputation and impair his ability to complete and publish the final results of his research efforts. Premature public disclosure of research is not harmful in this case alone, but will have an adverse affect [sic] on research into controversial areas conducted throughout the nation.” Meredith ruled that Bergdoll's deposition and documents introduced at the deposition be placed under seal. The case was settled before trial.

Procter & Gamble spokeswoman, Sydney McHugh, said that the ruling was significant because, for the first time, a judge heard Bergdoll himself describe what conclusions could be drawn from his research.

Meredith said that Bergdoll “is not associated with defendants. . . . He denies that his research will assist the jury in this lawsuit. Under the circumstances, his testimony and data will be excluded.” Riley, the plaintiff's attorney, contends, however, that because Bergdoll receives substantial support from Procter & Gamble, he “is not an impartial witness.”

Michael Liethen, legal counsel for the University of Wisconsin, who along with Procter & Gamble represented Bergdoll, rejects any suggestion that Bergdoll has been improperly influenced by Procter & Gamble. Liethen says that company money is paid to the university and the university then allots the money to Bergdoll. The company “ought to be congratulated for funding toxic shock research. The federal government doesn't support it. If not for P&G funding, the research wouldn't be done.”

Liethen says he is not sure what meaning the St. Louis ruling will have in other cases. “As a practical matter, each case has to be weighed on its own merits. In this case, there was extensive balancing of public and private interests.” Given the hundreds of toxic shock lawsuits still pending, the issue of Bergdoll's data and its use in court is far from settled.—MARJORIE SUN