Vivian Weil's Commentary on "Patent Authorship: Whose DNA Is It Anyway?"

Commentary On
Patent Authorship: Whose DNA Is It Anyway?

This case highlights the issue of fairness in listing inventors on a patent application from an academic laboratory. However, concern about a professor's fairness in wielding power over a graduate student appears to shape the presentation of the situation, with the focus on the professor, his student and their relationship. Omitting any introduction to the laboratory setting, the narrative reflects the isolation of the professor/student relationship, as if no one else is present and there are no practices or policies to guide decisions about patenting.

Only one detail refers to the world outside the laboratory and this professor/student relationship: the fact that the experimental work is to identify genes associated with heart disease. The potential for contributing to understanding and treatment of heart disease provides a basis for considering -- within the research group -- broad policy questions about openness and accessibility of research results. Apparently, no such discussion has taken place before Glen, the professor, asks Sarah, one of his graduate students, to carry out additional experiments on a cDNA he has cloned. Sarah is to characterize fully the importance of Glen's discovery.

Initially, this work is not part of Sarah's doctoral thesis. We do not know whether Sarah had already started another project for her thesis that might be put at risk by the new assignment. There is no indication that Glen discussed with Sarah the relation of the new assignment to her doctoral thesis. Even if he believes, on the basis of her prior work, that she is likely to succeed with the new assignment and will not be delayed in finishing her doctoral work, Glen has a responsibility to discuss this matter with Sarah.

Fortunately, Sarah's commitment to a major three-year effort on this project proves to be productive. Her progress in characterizing the gene is substantial enough for Sarah and Glen to prepare a manuscript for submission to *Nature*. Neither the

circumstances of submission nor the fate of the manuscript are mentioned again in Section 1. We do not know whether this omission indicates that the preparation of the manuscript is unproblematic or whether the writing of the paper is simply obscured by the patenting issues. It may be that procedures for manuscript preparation are better understood in this lab than policies and practices surrounding patenting, a relatively new option. That is not to say that there are no questions about Glen's management of authorship when in Section 2 he awards Sarah the position of first author on the paper.

Glen discusses with Sarah the commercial potential of the gene sequence she has helped to characterize, explains how he intends to patent the gene sequence through the university's technology transfer office, and speaks of the submission of "our patent." In this way, he leads her to expect to be included in the patent on the gene sequence. He seems to have offered no opening for a discussion of ethical issues associated with patenting. Although Sarah has "reservations" about the appropriateness of patenting her results, she is excited by the prospect of her first patent and keeps her reservations to herself. Her response is natural and unsurprising in view of her hard work over a long period and Glen's apparent comfort with patenting. Because reactions such as Sarah's are predictable, professors engaged in research with a potential for patenting have a responsibility to open discussion with graduate students about guidelines for patenting well before students become involved in the procedures. The occasion of transmitting oral or written guidelines concerning patent applications offers an opportunity to initiate discussion of ethical issues associated with patenting. It seems that Glen has not made a point of supplying guidelines, for Sarah has no knowledge of guidelines concerning patenting.

Professors engaged in research with potential for patenting have an ethical responsibility to give attention to patenting practices and policies: to formulate policies, to make sure that the policies are fair, that students are aware of the policies, and that students have an opportunity to consider the justification for patenting before they are drawn into the patenting process. Patenting should not be taken for granted as merely a component of scientific work like publishing. Since patenting confers proprietary control, it needs special justification. The patenting of discoveries related to human health has been an ethically controversial issue from the beginning of academics' efforts to patent their discoveries (early in the last century).For an account of earlier controversies about patenting in the domain of

medicine and health, see Charles Weiner, "Patenting and Academic Research: Historical Case Studies," in V. Weil and J. Snapper , eds., Owning Scientific and Technical Information: Value and Ethical Issues (New Brunswick, N.J.: Rutgers University Press, 1989). Senior investigators should expect and entertain probing ethical questions from thoughtful students. They should themselves have considered the pros and cons and be able to explain them in discussion with students. To fail to discuss ethically debatable procedures is to fall short in the transmission of ethical standards in science.

The failure to discuss such ethically debatable matters has significance beyond the impact on graduate students like Sarah who find themselves going along with procedures despite qualms about the ethical defensibility of what they are doing. Such failures contribute to an environment in science of treating unresolved issues of consequence to the welfare of society as if consensus already exists. Acting in this way, scientists help to settle important, controversial questions in advance of or in the absence of public discussion. By the time members of the public learn of and react to such developments as the patenting of genes, the developments have acquired momentum not easy to halt or slow down.

Failure to discuss relevant questions within research groups issue from and contribute to a climate that distances scientists from the social impact of their work. When public debate does occur, often scientists are not inclined to enter in with thoughtful contributions. They frequently fall back on the claim that they have no special expertise about the public's concerns. Such responses can be disingenuous when scientists have overlooked their own responsibilities to discuss issues (such as gene patenting in this case) within their research groups. Prior discussion within research groups might allow scientists to develop insights useful to the public debate.

These considerations notwithstanding, the question remains of whether Sarah has an obligation to raise questions about the patent process and manuscript generation. Intimidating as the graduate student environment can sometimes be, students have some responsibility for their own education. They have to learn how to ask questions, of whom and when. Timidity with respect to matters of appropriate behavior, particularly in the face of ethical doubts, has neither ethical nor prudential justification. Institutional policies may help to ensure that research groups in the institution have explicit policies and that students are informed about the policies. However, students, their professors and their institutions all have responsibility to

see that students are adequately informed about patent policies and practices.

It is only after Sarah becomes more deeply involved in the patenting process by generating additional data and providing this material to the university's designated law office engaged in drafting the patent submission that she learns she is not included on the patent. Because the application represents her manuscript, she at last confronts Glen. He defends his decision to make himself sole inventor, but not by referring to a policy or a practice. Instead, he points out that he made the initial discovery, that Sarah will be allowed to put the results in her dissertation, and that she can be first author on the publication describing the gene. Should these points convince Sarah that Glen's decision is fair?

If Glen has spoken plainly to Sarah in referring to "our patent," he has misled her to expect to be included in the patent. He owes her an explanation, if not an apology. His use of Sarah's manuscript as the basis of the patent application no doubt heightens her expectations. It is remarkable that Sarah could become so essential to the patenting process without getting clear information about whether she is to be included as an inventor and without asking direct questions on that point. Glen should not have used her manuscript for the patent application without making clear the terms. Misleading Sarah and taking advantage of her subordinate position are ethically objectionable. As a matter of prudence, Sarah should not have proceeded on a tacit understanding, counting on certain "signs" that she would be included as an inventor. If there was an oral agreement between Glen and Sarah that she would be included, Glen is ethically in the wrong for breaking his promise.

Because Glen has not previously made Sarah aware of any policies concerning patenting, his justification for making himself sole inventor appears to be *ad hoc*. He has not given her a basis for thinking he would decide another case similarly. Since her work is essential to the patent application, she might think he would have come to a different decision if she had raised the issue earlier. Though Glen may not have made a convincing case for his decision, Sarah apparently drops the matter and places her reliance on carrying out additional successful research. Without informing Glen, she performs more experiments to identify the human form of the gene. After identifying another closely related gene, she presents the data to Glen and then to her thesis committee. Now Glen instructs her to include the new material and agrees to include her as an inventor in a revised patent.

The outcome for Sarah is not damaging insofar as she is included in the patent, she can include the findings in her dissertation, and she can be first author on a joint paper with Glen. Nevertheless, she has had a damaging experience in other respects. She has experienced ethically objectionable treatment from her professor, and she has been exposed to neglect of standards in science, including ethical standards, that could undermine high ethical aspirations and trust. The experience could leave her cynical or discouraged about a career in science.

There are significant efforts in a number of scientific disciplines associated with codes of ethics, and there is perhaps a growing interest in an international oath of ethical commitment by scientists.The Standing Committee on Responsibility and Ethics in Science (SCRES) of the International Council of Scientific Unions is conducting a project in 2000-2001 to gather and analyze scientists' codes of ethics from all over the world. The committee aims to determine empirically whether there is a common core of standards. The American Association for the Advancement of Science (AAAS) is sponsoring a session on an international ethical oath for scientists at its February 2001 meeting in San Francisco. Nevertheless, in view of differences in local circumstances of research, conventions for awarding credit, authorship and inclusion in patents, among other matters, must remain relatively local. Principles such as those regarding authorship that have been promulgated by consortia of journal editors should inform local policies and practices. Research groups, however, must devise and announce their own conventions, policies and practices.

This case shows the damage that can result from negligence with regard to establishing local policies governing patenting: The student is left unprotected from the power of a professor. If Glen had in the end refused Sarah co-inventor status, Sarah would have been without recourse unless she was lucky enough to be in a position to appeal to university policies, a university office for dealing with conflicts over authorship and patents, a sophisticated, diplomatic department chair or another senior person with local influence. In her own research group, policies that might protect graduate students' interests are lacking.