Letters

Patenting DNA

The article "Genome patent fight erupts" (News & Comment, 11 Oct., p. 184) highlights the resistance to moving biotechnology in step with more established applied sciences. No one would pause to question applying for patent protection before publishing research on a new chemical compound or a mechanical or electrical advancement. The sad truth is that once publication has occurred without a patent filing date, U.S. and foreign patent rights are jeopardized and may be forever lost.

One point in the article requires clarification. It is asserted that Steve Bent and other patent attorneys are in agreement "that even if the first patent issues, subsequent ones will probably be harder if not impossible to obtain because the methods of generating these complimentary DNA sequences will become obvious and routine." This is a serious oversimplification of the patent process.

As long as the National Institutes of Health's (NIH's) later filed patent applications are copending with its seminal application (which may be a long period of time given the debate on the patentability of these "inventions"), the teachings of NIH's parent patent application cannot be used to render the inventions of its later patent applications "obvious." The only exception to this rule is that the NIH is not entitled to use later filed applications for "obvious" improvements to extend the patent term of its basic invention beyond 17 years. The NIH's worst-case scenario then becomes that improvement patent applications will have to include a "terminal disclaimer" of any patent rights after expiration of the seminal patent. This means that no matter how "obvious" the process may have become, the NIH stands to gain substantial patent rights for every patent application it files before issuance of its first genome patent.

The NIH should be applauded for attempting to take an aggressive patent stance that should benefit U.S. industry as a whole.

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The suggestion to patent DNA sequences is one of the most ludicrous propositions I've ever heard. These sequences are in no significant way different from other data gathered by scientists. I am a behavioral ecologist, and I study parental care in birds. I have found that the roles of the sexes differ in biparental components of care in songbirds. Should I now "patent" my findings so that when my work is cited, I receive a check in the mail? Of course, this is ridiculous. Yet, the only difference between my data on parental care and DNA sequences is that the latter smell of big business and big money. If someone had to pay me to cite my findings, they would instead glibly eliminate the citation. What we are now witnessing is quite clearly the 1980s American business mentality transfecting the 1990s molecular genetical–biomedical sciences.

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Rather than plunge into the costly and uncertain battle for patent protection of DNA sequences of unknown value, the National Institutes of Health should consider alternative intellectual property protection for the sequence data generated by the Human Genome Project. The Copyright Act of 1976 provides a useful model: the compulsory license. In five specific situations (secondary transmissions, nondramatic musical works, jukeboxes, public broadcasting, and satellite transmissions), a statutory license may be obtained to use an author's work without express permission, as long as the copyright owner is informed and a fee is paid. A compulsory license for DNA sequences would achieve an efficient balance between public access to government information and the private sector's interest in exploiting science for monetary gain.

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Alar's Risks

Eliot Marshall's News & Comment article "A is for apple, Alar, and . . . alarmist?" (4 Oct., p. 20) presents a provocative analysis of the continuing debate over Alar's risks, as well as the broader debate over current scientific methods for assessing the risks of pesticides used on food. I am concerned, however, because the article omits the important point that the Environmental Protection Agency (EPA) still believes, on the basis of a risk and benefit analysis, that Alar's risks would be unacceptably high.

In 1989, when EPA issued interim risk estimates for daminozide (Alar) and its byproduct UDMH (unsymmetrical dimethyl hydrazine), we made it clear that we were basing this assessment on the first-year results from 2-year rodent studies that were scheduled to be completed in 1990. At that time, EPA said that these risks were too high, and we proposed the cancelation of Alar. As we all know, Uniroyal subsequently canceled its Alar food use products voluntarily after the public outcry.

As Marshall's article indicates, EPA recently reduced its 1989 estimate of UDMH's cancer potency (Q*) by about one-half, after evaluating the final results of the rodent studies. This kind of change is not unusual or unexpected when early projections are involved. More important, in this case the change in Q* does not change EPA's earlier conclusion that, although Alar has some benefits, its dietary risks from historical exposures are unacceptably high. Yes, Alar appears somewhat less risky than we thought in 1989. But no, that lower cancer potency estimate would not lead EPA to reverse our regulatory position.

While Alar has become a symbol of the food safety controversy, the debate involves broader issues of how EPA assesses and manages risk. It is true that the U.S. regulatory community differs from the European community in our approach to hazard and risk assessment. But it is important to articulate the reasons why EPA and other U.S. agencies generally take a more cautious and conservative approach.

Characterizing risk is not an exact science: uncertainty is inherent in the estimation of risk regardless of the methodology used. Deciding how to deal with that uncertainty—and thus which animal models, exposure scenarios, and means of extrapolation to use—is ultimately a matter of making value judgments as well as doing science. U.S. agencies have historically taken a conservative approach to cancer risk assessment and decision-making.

EPA has chosen this path for good reason. We believe it is consistent with our mandate to protect human health and the environment, and we believe it is what the public expects and deserves.

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One Tomato, Two Tomato . . .

Because I'm not that far removed from the grand climacteric, my first glance at the two sets of identical tomatoes on the cover of the 18 October *Science* had me worried that

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