

CORRESPONDENCE/

Patents on Gene Fragments

To the editor:

Kurt MacLean argues that the filing of patent applications by NIH on thousands of human gene fragments represents "sound public policy" and will "provide a solid foundation for the flourishing of the private genetic engineering industry" (*Bio/Technology* 10:600, "NIH Gene Patents: A Solid Foundation for the Industry"). He reasons that royalties from licenses to private firms will help the federal government to recover the expenditures of the Human Genome Project, providing a "financial return to the taxpayers" that will make Congress more willing to foot the bill for other Big Science projects in the future. Private industry will benefit from the resulting increase in government funding for future research, as well as from the public disclosure of NIH discoveries through the patent system.

Mr. MacLean fails to appreciate the role of NIH as a public institution. This is most apparent in the bizarre assumption that if NIH were not compelled to disclose its inventions in order to obtain patents, it would maintain the results of genome research as trade secrets rather than disclosing the information through scientific publications. Given that NIH scientists are well motivated to publish their research results, it is more likely that NIH's policy of pursuing patent rights will delay disclosure of discoveries by compelling scientists to confer with patent attorneys and wait for patent applications to be filed prior to publication.

The argument for NIH patents as a mechanism for providing a financial return to taxpayers on their investment in research is similarly flawed. Indeed, if the prospect of generating royalty income has motivated NIH's decision to pursue patent rights, it certainly has not featured prominently in public statements by NIH representatives in support of its actions, nor should it carry much weight in considering the soundness of NIH patent policy from the standpoint of the taxpaying public. The fallacy in this prong of MacLean's argument is that the public has to pay the royalties in the form of higher prices on patented goods and services in order to collect them in the form of contributions to the federal fisc. At best, the transaction will be an overall wash; more realistically, the administrative costs of obtaining and enforcing patent rights will result in a net loss to taxpayers and consumers, with a corresponding gain to patent attorneys.

According to Bernadine Healy, the purpose of the patent applications is not to make money, but rather to see to it that NIH discoveries are translated into useful products. By patenting the sequences and offering exclusive licenses to private firms, NIH seeks to ensure that firms will be willing to make the necessary investments to develop related products. It is by safeguarding the profits of the private firms who develop these products, rather than by diverting these profits to the federal government in the form of royalties, that the public stands to benefit from the NIH patents.

Whether the patent rights that NIH is seeking will in fact promote technology transfer and investment in the development of genome-related products in the private sector turns on empirical questions about the functions of the patent system that have no clear answers. One important question is whether private firms would have adequate incentives to invest in product development without the NIH patents. If, as Mr. MacLean urges, companies that wish to exploit the NIH-patented genes commercially may obtain use patents

for any uses of those genes that they discover, then exclusive licenses under NIH patents may be unnecessary to protect their market positions. Rather than serving to protect the profit margins of the innovating firms, the NIH patents may merely add to the thicket of patent rights that firms have to negotiate their way past in order to bring new products on the market.

At their best, patents promote investment in research and development by enhancing the profits of innovating firms. At their worst, patents stifle research and development by weighing firms down with heavy royalty burdens and confronting them with legal obstacles that they must overcome before they can sell new products. Whether the potential benefits of the patents NIH seeks will outweigh the potential detriments is not at all obvious at this stage of the game. In the face of this uncertainty, concerns raised by industry representatives that the patents will inhibit private sector research and development deserve the serious consideration of public policymakers.

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To the editor:

Kurt MacLean (*Bio/Technology* 10:600 "NIH Gene Patents: A Solid Foundation for the Industry") tells us that the NIH could "provide a rationale" for continued government funding of Big Science by filing for patents on partial sequences of randomly selected cDNA clones. Filing for these patents, he writes, "will provide financial returns [that] would certainly improve the chances that the NIH will succeed in selling its next Big Science proposal to Congress."

I will not delve into the dubious value of selling to Congress another Big Science project, nor will I discuss the dubious logic behind the legal arguments in favor of patenting these DNA fragments, which seems to be based on the claim that the cDNA clones are "compositions of matter" that will (probably) eventually be part of some unspecified invention. I would, however, like to mention that by filing these patent claims, the NIH tacitly favors the broadest possible view of patenting biological materials. Patents this broad certainly WILL slow the flow of information within the scientific community, Mr. MacLean's demurrals notwithstanding. And the patenting of cDNA clones is likely to make basic research more costly, since the most common eventual use of these clones and their products is likely to be in the area of basic research itself, rather than in consumer-oriented drugs and other products. Providing exclusive licenses to suppliers of research reagents will be an unfortunate and unnecessary addition to their cost. Currently most natural products which researchers buy from private vendors are not covered by patents.

Related to the specific issue of whether cDNA clones should be patented is the more general issue of whether the NIH should actively pursue commercial research involvement. An ideology has been developing in Washington, justified primarily by an oversimplified view of the basis of current Japanese economic success, that government should move toward funding applied commercial research. There is a clear danger inherent in this trend—a danger that government will cease to fund the most productive area that it is uniquely qualified to fund—innovative, small-scale, broadly targeted basic research. Private capital can and will