nature biotechnology
VOLUME 19 • NO 3 • AUGUST 2001



# Rights of access

Biotechnology tends to be the preserve of the world's richest nations. It is the rich who run biotechnology companies, it is the rich who fund them, and it is the rich who consume their products. Developing countries don't really get a look. Biotechnology's medicines are too expensive. Its patented crops and seeds are too inaccessible. And, in any case, for the most part, those products are not the medicines and crops that people in developing nations want or need. It should not come as a surprise to any one that the priorities of the rich, capitalist nations are not those of the rest of the world. Of a total $70 billion spent on health care research worldwide in 1998, for instance, only $100 million was set aside for malaria research (about a tenth of the cost of the US Department of Defense's recent "experiment" of intercepting a ballistic missile with a ground-launched exo-atmospheric kill vehicle).

Without doubt, the developing world could benefit from biotechnology. The world's poorest nations are home to 98% of all children who die before their fifth birthday (many from malnutrition and starvation), and 99% of all people who succumb to infectious diseases like tuberculosis, measles, tetanus, diphtheria, and whooping cough. Crassly, one could define these needs as "market opportunities". The argument is certainly being made—most recently in a Human Development 2001 report from the United Nations—that poorer countries should make biotechnology development an urgent priority.

But many are saying that inequities in the patent system—particularly the World Trade Organization TRIPs (trade-related aspects of intellectual property rights) agreement—are repressing biotechnology in poor countries, allowing multinational corporations to establish monopolies, drive out local competition, divert research away from the needs of poor countries, and force up the prices of drugs and seeds. The recent wrangles between Western drug companies and the governments of South Africa and Brazil (see p. 698) are a case in point.

What seems to be getting lost in all this is that a balance must be struck between the rights of rich-world companies to recoup the cost of developing (both successful and failed) products and the plight of nations too poor to buy the products they need.

Biotechnology is difficult enough to achieve in places where markets are lucrative, R&D spending is high, and commercial practices are predictable. It is hard to imagine how it can succeed in countries where R&D expenditure is a fraction of GDP (usually less than a quarter of that in developed nations), skilled and educated labor is at a priority, inflation is rampant, investors fear for their property rights (or lives), and political turmoil is constant.

In this environment, it might be appropriate if there was a formal commitment to be more flexible about the imposition of intellectual property on researchers in developing countries. We must give developing world research a chance to foster its own biotechnology to address its own problems. Once these countries have formed an industrial base mature enough to foster homegrown innovation, patent enforcement will become a matter of urgency and self-interest for them as well. That is the time when a level playing field for global intellectual property barriers will be appropriate.

# Monstrous crowing

Two of the world's largest producers of biopharmaceuticals, Biogen and Serono, have been keeping their lawyers busy again with claims and counterclaims about the effectiveness of their respective interferon beta-1a products used by people with multiple sclerosis (MS; see p. 696). Both preparations are effective at the relapsing/remitting stage of the disease in reducing the severity or the frequency of relapses.

To an extent, though, Biogen and Serono now appear to be arguing about the number of angels that can fit on the head of a pin. The dispute concerns the result of a head-to-head trial indicating that patients on Serono's drug had fewer relapses over a six-month period than those on Biogen's. Biogen representatives have criticized the trial design, the data analysis, and its presentation. They have countered also with data that show their beta-interferon caused fewer immunogenic side effects. Biogen's lawyers have filed a criminal complaint asserting that Serono infringed an injunction preventing Serono from making "misleading claims" of superior efficacy. Serono then filed a civil complaint claiming that Biogen was trying to prevent dissemination of scientific data and manipulate the media. At stake for the companies is a slice of the US multiple sclerosis market. Biogen has two more years of market exclusivity in the United States under the Orphan Drugs Act—worth perhaps half a billion dollars a year to the company—and Serono can only gain access before that time if it can show that its drug has superior performance.

What both companies appear to have forgotten in their relish for a legal battle is that there are many people out there—in excess of 200,000 MS patients in the United States alone—for whom the stakes are significantly higher. No amount of vociferous and obnoxious legal jousting can obscure the reality that the Tweedledee and Tweedledum of beta-interferon are arguing over a rattle that, as a drug, is already broken. Both versions do no more than delay the onset of the more debilitating phase of the disease. They nudge the disease onto a more favorable, but still downward path. They do not stop it, or reverse it.

To be fair, both companies have potential MS treatments in the pipeline. Biogen, working with Elan, has an anti-autoimmune antibody in phase 2 trials. Serono has some small-molecule compounds under investigations through collaborations with British Biotech and Vertex. No doubt all these projects are receiving copious management attention. But that is not the impression that the legal wrangling gives.