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THE FIRST WORD/

DOUBLE-DEALING AND DUBIOUS CLAIMS

In "Checking Sources: The Serum Supply Secret," senior editor John Hodgson gives an early warning about storm clouds gathering over the supply of fetal bovine serum. National health policies—and national prejudices—have combined of late to greatly restrict the number of generally acceptable sources of FBS. Constraining the supply has obviously increased the demand for serum from these premium suppliers. But at the same time, the inconsistent, spottily enforced national regulations have offered heavy inducements for unscrupulous profiteers—and have created a maze of international back alleys through which they can maneuver mislabeled serum and cash in on the higher margins.

Let us say here, as Hodgson is at pains to make clear in his article, that this deception is practiced by only a small minority, mostly fly-by-night serum dealers.

But the mere existence of this adulterated trade strikes at the heart of pharmaceutical biotechnology. The very complexity of the biologicals we deal with has driven us to extreme lengths to satisfy the regulators' demands for the secular trinity of quality, safety, and efficacy.

As long as any of the debasers continue to profit by deception, they threaten the integrity of every biopharmaceutical manufacturer. So far, the clearest warnings and complaints about adulterated serum have come from the biopharmaceutical industry itself. Inexplicably, regulatory agencies—notably those outside the U.S.—have ignored warnings from biotech executives and reputable serum dealers. Can they be so blind to the well-being of the biopharmaceutical industry (which would be understandable, perhaps, though the industry is an important natural resource in every nation that supports it)? Can they be so unconcerned about the welfare of their own citizens (which would be unconscionable)?

Through the Looking Glass. In one of the most inspired acts of possession since Columbus erected a cross on Samana Cay (or whichever island it really was), a single June 20 patent filing by Craig Venter laid claim to 337 human genes parsed by his cDNA-sequencing factory at the National Institutes of Health. Since then, his lab has sequenced another 2,000 genes or more—potentially planting NIH's flag on some 2 percent of human genes.

The very idea is outrageous, of course. The genes have no known utility (one of the cornerstones of patentability). And once the technology for cDNA sequencing is known, there is no originality to the brute-force sequencing. Most experts feel that this largest-ever patent filing has little to recommend it.

But we have long since learned that scientific common sense has little to do with the the Lewis Carroll world of patent law—like *Through the Looking Glass*, a realm where profuse invention meets a logician's fantasy. Moreover, as Mimi Bluestone points out in her Dateline article, "Patenting Human Genes Raises a Storm," NIH is in a difficult position: To avoid the criticism leveled at researchers from Fleming to Koehler and Milstein to the NIH developers of AZT, they may *have* to file claims at every opportunity. Otherwise, the argument goes, they could forfeit forever their rights to discoveries down the road.

(Broad claims seemed to be in vogue last summer. We noticed that an over-the-counter company named Currentsea [currency, get it?] last July claimed title to ten percent of the world's oceans, according to the October 28 *Forbes*.)

Still, on considering NIH's "omnibus human genome patent act of 1991," we dusted off our own application—titled "Breathing"—hoping to own Venter before he owns us. Ridiculous.

Tool Kits. Elsewhere in this issue we offer "A new generation of animal cell expression vectors," which could give existing cell-transfection systems a run for their money.

We also offer a complete and novel tool-kit for those who work with monoclonal antibodies: a new method for targeting recombinant antibodies to bacterial cell surfaces (with great promise for highly efficient isolation); an extremely neat, near-universal technique for linking IgG molecules to biotin or biotinylated substances without chemical modification; and a new phage-presentation system for rapid screening of F_{ab} fragments.

And that's far from all. We think of this issue of *Bio/Technology* as a holiday gift. We hope you enjoy it

—Douglas McCormick