

would be contrary to public policy or morality. . .” going on to state [sub-paragraph (c)] that “Processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal” shall on this basis be unpatentable. That is, patents would only be refused where suffering to the animal outweighs any benefits to mankind or animals. Article 3 of the amended draft excludes “plant and animal varieties” but this is nothing new and is a mere repetition of Article 53(b) of the European Patent Convention (EPC), which was narrowly construed by the European Patent Office in the Harvard Mouse case. To quote from the Commission’s Explanatory Memorandum: “In view of the usefulness of this type of invention to man’s well-being, in this instance his health, the Commission considers it only right and proper that investment in research thereon should be capable of being duly protected. The Commission also considers that the borderline between what is acceptable and what is not acceptable must take account of the criterion of animal suffering.” It should also be noted that the Commission in its Explanatory Memorandum has sensibly rejected a Parliamentary amendment under which the performance of inventions considered to be “contrary to public policy or morality” should be banned as the Commission considers that this “goes beyond what patent law can monitor by way of the examination of patent applications filed with national offices.”

Second, there is no express exclusion of the patenting of cDNA sequences. Rather, Article 2.3 sub-paragraph (a) excludes “the human body or parts of the human body per se” on the basis that the exploitation thereof would be contrary to public policy or morality. The wording of this exclusion is vague and uncertain in its scope to say the least and I hope that the Council will consider further clarification. The Commission’s Explanatory Memorandum states that it “wishes to make it quite clear, ... that ‘parts of the human body per se’ means parts of the human body as found inside the human body.” Certainly, this is not clear from the present wording. The Explanatory Memorandum goes on say that the intention here is not to change the position with regard to certain products or parts of the human body which are already covered by patents, e.g., a human lymphoblastoid cell line (EP 0,113,769) or a recombinant vector coding for human beta-interferon (EP 0,041,313); rather the intention is to exclude patents, for example, for human genes whose function or whose corresponding protein is not known—apparently an oblique reference to the “Venter” controversy.

Third, the amended draft does not intend to change the position of “discoveries”: that is (under the EPC) “discoveries as such” are not patentable. Article 7 of the amended draft merely clarifies that position by stating that “an invention concerning a biological material shall not be considered a discovery or lacking in novelty for the reason only that, although not known, it formed part of any existing material.”

Gerald Kamstra, Partner
Simmons & Simmons
14 Dominion Street
London EC2M 2RJ, U.K.

HIV Latency

To the editor:

According to Stephen Edgington, Anthony Fauci has recently announced his discovery that HIV is never truly latent between infection and the development of AIDS (*Bio/Technology* 11:16-17, January). No complete comment is possible, of course, until these results are published. Nevertheless, even if one takes this indirect report at face value, the results only seem to confirm the hypothesis that HIV does not cause AIDS. First of all, Edgington cites the hypothesis that HIV produces viremia in AIDS patients, after having remained dormant for an average of ten years. This hypothesis, however, has long been disproven. Even in end-stage AIDS progression, viremia is virtually never observed; indeed in at least half of all AIDS cases, no HIV expression can be detected (Duesberg, P.H., 1992, *Biomed. Pharmacother.* 46:3-15).

Fauci reports three observations, all of which argue strongly *against* the HIV hypothesis: (1) He finds HIV virions localized in lymph nodes of infected individuals—all coated and completely neutralized by antibodies! As we have previously pointed out, this is the proof that the immune system is effective at neutralizing HIV, rendering the virus noninfectious and preventing viremia. Yet AIDS often occurs anyway, without any viral reactivation. Some other factor must cause AIDS instead. (2) He observes necrosis in follicular cells during progression to AIDS—but admits that “Since there is no virus production that amounts to anything, there must be something other than the virus causing them to die.” Exactly the point! (3) He also points to HIV infection in human thymic transplants in scid-hu mice, suggesting this might mean HIV infects T-cell precursors in humans. But the transplanted immune systems in these mice are not destroyed by the virus (Namikawa et al., 1988, *Science* 242:1684-1686). Further, a reservoir of HIV infection has never been found in human T-cell progenitors, merely the same low level of dormant HIV provirus (Schnittman et al., 1989, *Science* 245:305-308). And even if such reservoirs did exist, HIV would be unable to kill the cells; Montangier and others have confirmed that HIV, like all retroviruses, is not cytotoxic (Lemaitre et al., 1990, *Res. Virol.* 141:5-16).

We do not propose that Fauci receive Edgington’s proposed award for “confront[ing] the issue of HIV pathogenesis” until Fauci is willing to engage the issue of *whether*, not *how*, HIV causes AIDS, and whether AIDS is even an infectious disease at all.

Peter H. Duesberg
Department of Molecular
& Cell Biology
University of California
Berkeley, CA 94720

Corrections

February’s article “Virus Harvesting and Affinity-Based Liquid Chromatography” neglected to mention that the study was conducted at the Division of Laboratories at Tufts University School of Veterinary Medicine, North Grafton, MA. And footnote 6 indicated on p. 173 should have been footnote 5.

The first sentence in January’s article “Assessing a First-to-File Patent System” should have read, “Pending legislation would change the U.S. first-to-invent patent system to a first-to-file system.”