

/CORRESPONDENCE

Proof of Utility*To the editor:*

In the correspondence section of the November 1994 issue (*Bio/Technology* 12:1048), Mr. Gabriel P. Katona of Schweitzer, Cornman & Gross, in discussing the requirement for proof of utility in U.S. patent applications directed to the treatment of AIDS, stated "claims to curing cancer in general, and the curing of AIDS, in the absence of more than usually stringent evidence to the contrary, are viewed by the PTO [U.S. Patent and Trademark Office] as 'unbelievable' utilities. . . ." Although the treatment of AIDS may still be considered unbelievable by the PTO, the treatment of cancer no longer is and has not been for a number of years.

As long ago as 1986, the PTO Board of Patent Appeals and Interferences held that the treatment of cancer *per se* is not unbelievable or incredible. See *Ex parte Rubin*, 5 USPQ2d 1461 (BPAI 1987) and *Ex parte Krepelka*, 231 USPQ 746 (BPAI 1986), which both reversed the examiner's position that the recited utility is unbelievable *per se*. That is, the standard of burden of proof of utility, as in all other believable arts, is appropriate.

As a patent attorney who has successfully argued before the PTO that the treatment of cancer is not unbelievable, I believe that your readers should know that, as to patent applications regarding inventions directed to the treatment of cancer, they have alternatives to submitting voluminous evidence of utility to satisfy an examiner who is not up-to-date with "contemporary knowledge" (see *Rubin*).

At some point in the future it is likely that the PTO position as to the believability of the treatment of AIDS will also change. To those who have patent applications in this art, it is vital that you or your patent counsel keep up with the published court and board decisions to determine when such a change occurs.

On another note, Mr. Katona indicates that perpetual motion machines are viewed in the same manner by the PTO as treatments of cancer or AIDS. Although a utility as a perpetual motion machine is indeed also considered unbelievable, the standard of evidence required is much greater than in the treatment of AIDS. Specifically, when the recited utility is as a perpetual motion machine, which as a concept is contrary to the laws of nature as we believe them to be, a working model of the machine must be presented, demonstrated, and independently tested. Declarations or affidavits executed by the inventor that a claimed machine operates as a perpetual motion machine are not sufficient to establish the utility thereof. Thus perpetual motion machines are not viewed by the PTO in the same manner as treatments of cancer or AIDS. The courts have upheld the appropriateness of the requirement of the U.S. commissioner of patents and trademarks for working models of perpetual motion machines.

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A Stabilizing Influence*To the editor:*

The article "Trehalose is a sweet target for agbiotech" (*Bio/Technology* 12:1328, December) gives the readers the impression that trehalose is a sweetener. Approximately half the people who taste trehalose sense sweetness at about 0.3 times the intensity of sucrose. It may be that these people have trehalase in their saliva and so they are in fact tasting the sweetness of glucose. It would be an interesting project for one of your readers to investigate this further. The other half of trehalose-tasters do not sense any sweetness at all.

The functionalities of trehalose that are considered interesting for food applications are: its nonreducing character, chemical stability at high temperatures (i.e., above 140°C), glass forming, and low sweetness profile. Thus trehalose can be used for bulking in "healthy" foods or for stabilizing and preserving volatiles and pigments that can give food-stuffs an outstanding "fresh" character (*Trends Food Sci. & Tech.* 2:166).

Trehalose is a non-reducing sugar and, unlike sucrose, does not hydrolyze to reducing sugars under normal conditions of food processing. Thus trehalose does not undergo Maillard reactions with amino groups (the so-called non-enzymatic browning reactions). While the Maillard reaction can improve the flavor and appearance of food (e.g., barbecue steak), it is also a major source of deleterious change during the processing of food-stuffs and especially during drying. You only need to compare the flavor profile of fresh basil with dried basil to notice the effect of processing. Trehalose also appears to inhibit the Maillard reaction cascade at low water activities, an aspect of trehalose chemistry that deserves further research.

The main utility of trehalose in food processing is as a stabilizer of "fresh" character, but similar stability has been obtained with many pure molecules and systems; e.g., enzymes, antibodies, pharmaceuticals, antibiotics, viruses, and cells (*Biopharm* 4:47; *Bio/Technology* 10:1007, October, 1992). The availability of robust active forms of previously unstable biomolecules opens doors to exciting possibilities for biotechnologists working in fields such as pharmaceuticals, diagnostics, biosensors, and bioelectronics.

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REASONS

"You see, then the RNA measurement comes out here wrapped in a fortune cookie. The more playful machines include eggrolls."