House Subcommittee OK's Restoration



Supporters of restoration (clockwise Reps. Butler, Sawyer, Railsback and Staffer, Kastenmeier)

The House Subcommittee on Courts, Civil Liberties, and the Administration of Justice voted 5–1 in favor of H.R. 1937, the Patent Term Restoration Act on March 25. Voting in favor of the bill were Representatives Kastenmeier, Railsback, Brooks, Sawyer, and Butler. Congressman Barney Frank (D-MA) was the single "no" vote.

Up until the last minute there was a great deal of confusion on whether or not the Subcommittee would consider the legislation which restores patent life lost to government regulatory reviews. Such products could apply for and receive additional patent life if the agency clears them for marketing.

The Subcommittee found itself reconsidering a cable TV-copyright bill which had previously been approved but which was returned to it from the full Judiciary Committee on a point of order. This cast doubt on whether there would be enough time to approve both bills. However, once a quorum was present the markup of both bills went very quickly and both were approved.

Congressman Kastenmeier, the sponsor of the restoration bill, began the session by introducing a number of amendments. As explained by Mr. Kastenmeier the amendments:

- Grant patent restoration to the "recipient of market approval" (owner or licensee) rather than the owner of the patent.
- Limit restoration to a 27-year period beginning with the date a patent is first *filed* anywhere in the world. Limits restoration to six months for each year of regulatory review which occurs more than ten years after a patent is first *filed.*
- Postpone the regulatory review trigger date from IND filing to the initiation of a "clinical trial on humans for the specific method for use for which the product is approved. . . ."
- Delete provision permitting patent restoration for products *other than* food additives, pharmaceuticals, medical devices and chemicals.
- Deny restoration to any product on which a *patent is issued* prior to date of enactment.
- Permit retroactive restoration to products subject to more than seven years of regulatory review during which a major carcinogenic test was required (applying only to a product marketed by Airco).

The amendments were accepted with only Representative Butler voting "no".

The Subcommittee also approved two amendments offered by Mr. Railsback which extended coverage to genetic process patents and for the inclusion of Aspartame, a low calorie, dry sweetner developed by G.D. Seale & Co. which had its approval stayed for 5 years in the Food and Drug Administration.

Congressman Frank attempted to attach three weakening amendments to H.R. 1937 which were drafted by Representatives Henry Waxman (D-CA) and Albert Gore (D-TN), critics of the bill. Waxman and Gore wrote a letter to Kastenmeier two days before the Subcommittee consideration urging defeat of the legislation because it would unfairly hurt consumers, especially the elderly. The letter also quoted from studies by the Office of Technology Assessment alleging that there has been no drop-off in pharmaceutical research and development and that much of the time lost was due to the companies slowness and not to government regulations.

The first Frank amendment would have reduced the time period that could be restored and was voted down 3–1. The next amendment allowed generic drug companies to copy the size, color and shape of drugs coming off patent so that the products could be identically copied. Kastenmeier agreed with Frank that this would be beneficial to consumers and voted for it, but Congressmen Butler, Sawyer and Railsback voted the amendment down. Frank indicated that he would hold his other amendment dealing with speeding up the FDA approval of generics until the full Judiciary Committee considers the legislation.

The Senate has already approved its version of the legislation. Consideration by the House Judiciary Committee has not yet been scheduled.