Restoration Moves Toward Committee Vote

Indications are that the House Judiciary Committee will take up the Patent Term Restoration Act by the middle of the month. Bill sponsor Representative Robert W. Kastenmeier (D-WI) introduced a clean bill May 20 reflecting changes made in his Subcommittee March 25. The legislation is now H.R. 6444.

Debate on the merits of the legislation are growing more heated. Basically, the legislation provides that products delayed from reaching the market because of federal regulatory clearances are eligible for having up to 7 years restored to their patent life if they are approved for marketing. The time restored would be equal to the time spent before the agency on the theory that the 17 year patent term should not be significantly reduced by premarketing clearance procedures. The legislation would have its primary effect on pharmaceutical and chemical products.

The legislation, which is endorsed by IPO, faces bitter opposition from generic drug companies and public interest groups viewing it as an attempt to force higher drug prices for longer periods of time on the public. In the Subcommittee markup Representative Barney Frank (D-MA) offered a series of weakening amendments supported by bill opponents Representative Albert Gore (D-TN) and Representative Henry Waxman (D-CA) which were rejected. Frank was the lone Subcommittee vote against the measure.

Representative Kastenmeier seeking to mollify the opponents attached a series of amendments to the bill, two of which have proven especially worrisome to businesses and universities. Amendment number 5 denies restoration to any product which has been patented prior to the date of enactment of the bill. This would mean that there could be no benefits under the legislation until 1999 when the normal 17 year patent for products issuing in 1982 would expire. The amendment is based on the theory that restoration should encourage future innovations and that patents which are already issued will be developed without any extra stimulus. This view is not shared by innovators who counter that the fact of patent issuance hardly insures development of a product. Furthermore, with the Food and Drug Administration by its own admission routinely taking 7 years to clear drug applications, many products with limited markets may not be developed because the time necessary to recover costs simply is not present.

Such discouragements, it is argued, really hurt the public which is denied new products and therapies, many of which affect patient populations too limited to justify development unless there is a full patent term to recover costs.

The second amendment which concerns universities states that restoration will be owned not by the patent owner but by the "the recipient of marketing approval." The rational behind this Kastenmeier amendment is that many times U.S. companies are licensees of foreign concerns and the restoration period should be owned by the American company. Unintentionally, the amendment seems to have the primary effect of hurting universities who also license their discoveries and would be denied ownership of the restoration under the amendment. The chemical industry is also concerned with the amendment because under the Toxic Substances Control Act, for example, there is no marketing approval.

Representative Tom Railsback (R-IL) indicated in a speech May 24 at the Bureau of National Affairs Patent and Trademark Day that he would be offering several amendments in the Judiciary Committee to restore the original intent of the bill. IPO and a number of universities and businesses supporting the restoration concept are supporting Railsback's efforts.

"§ 155. Restoration of patent term

"(a)(1) Except as provided in paragraphs (2) and (3), the term of a patent which encompasses within its scope a product subject to a regulatory review period, or a method for using such a product or a method for producing such a product, subject to a regulatory review period shall be extended if—

"(A) the recipient of marketing approval gives notice to the Commissioner in compliance with the provisions of subsection (b)(1);

"(B) the product or method has been subjected to a regulatory review period pursuant to statute or regulation prior to its commercial marketing or use;

"(C) the patent to be extended has not expired prior to notice to the Commissioner under subsection (b)(1); and

"(D) the patent to be extended was issued on or subsequent to the date of enactment of the Patent Term Restoration Act of 1982.

The rights derived from any claim or claims of any patent so extended shall be limited in scope during the period of any extension to the product or method subject to the regulatory review period and to the statutory use for which regulatory review was required.

"(2)(A) Subject to subparagraph (B), the term of the patent shall be extended by the time equal to the regulatory