2.5.18 Product-by-Process Claims

A product claim that defines the claimed product in terms of the process by which it is made: A product made by the process comprising of steps... Patentability based on product itself and NOT on the method of production. If the product is the same (as prior art), using another process does not make it patentable. If examiner shows that the product appears to be the same or similar, the burden shifts to the applicant; the United States Patent and Trademark Office bears lesser burden of proof in making out a case of prima facie obviousness. One-step method claims are acceptable, but claims where body consists of single "means" elements are not acceptable.

2.5.19 Patent Term Adjustment

The United States Congress passed legislation known as the Hatch-Waxman Act in 1984. It weakened patent law for pharmaceuticals, making it easier for generic copies to enter the market based on the innovator's safety and effectiveness data. Under the act, pharmaceutical research companies lost nearly all of their rights to defend their unexpired patents before generic copies entered the market. Patent holders can sue to defend their unexpired patents *only* when a generic drug manufacturer submits a filing to the FDA, seeking to bring the generic copy to the market. The act also created a 30-month stay procedure to allow patent holders the opportunity to obtain a court ruling on whether the generic copy infringes their patent. Thirty-month stays do not extend patents—they are triggered *before* the patent expires and provide a period of time during which patent infringement cases can be resolved.

Patent lawsuits based on the act are rare, because generally, challenges to patents on prescription medicines are rare. The FDA reports that of 8,259 generic applications filed between 1984 and 2001, only 6% raised a patent issue, the necessary condition for patent litigation. According to the Federal Trade Commission, more than one-quarter of patent challenges studied did not result in a lawsuit by the innovator company. Since enactment of the law, generic company share of prescription medicine use has increased from 19% of prescription units in 1984 to 50% today.

The average effective patent life for prescription medicines under the Hatch-Waxman Act is 11–12 years, compared with an average of 18.5 years for other products.

With effect from August 18, 2003, the FDA revised its regulations as follows:

It permits only one 30-month stay in the approval process for a generic drug pending resolution of patent litigation. Past regulations acquiesced to the delayed launch of generic versions beyond 30 months, when there were multiple, consecutive patent challenges that were made against the launch of the generic versions, even if the challenges were frivolous.

It clarifies the types of patents that may be listed in the "Orange Book," which is the FDA's official register of approved pharmaceutical products that provides notice to generic drug makers of name brand patent rights. Patents that cover drug packaging or other minor matters not related to effectiveness may no longer be listed. Patents that pertain to active ingredients, drug formulations/compositions, and approved uses of a drug are to be listed. A more detailed, signed attestation will be required to accompany a patent submission. False statements in the attestation can lead to criminal charges.