



Apotex USA, Inc. v. Merck & Co., 254 F.3d 1031 (Fed. Cir. 2001)

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CASE FACTS

- Apotex’s patents cover a process for making an enalapril formulation (high blood pressure drug).
- Merck has been selling enalapril (VASOTEC) since 1983.
- Merck owns a product patent but does not own a manufacturing process patent.
- Later, Merck disclosed ingredients of the enalapril formulation:
 - in a French pharmaceutical dictionary (1988);
 - in a Canadian product monograph (1992); and
 - in a Canadian trial (1994).
- After the Canadian trial, Dr. Sherman, an Apotex official, allegedly conceived the process.

ISSUE

1. Can Merck rely on activities outside the US to deny suppression or concealment in 102(g)?
2. Should Apotex’s patents be invalidated based on Merck’s activities?

HOLDING

1. Yes
2. Yes

ANALYSIS

1. Activities outside the US

The plain language of 102(g) and legislative history lead to the conclusion that the language “in this country” only modifies “the invention was made” and that the proof to deny suppression or concealment is not limited to activities in the US.

2. Suppression or concealment

- Merck's suppression or concealment is inferred because Merck took no steps to make the invention publicly known for 5 years.
- However, the inference can be overcome by the first inventor's (Merck) resumption of activity before the conception of the second inventor (Apotex).
- Merck disclosed the ingredients and process before Dr. Sherman's conception.

NOTE: (burden of proof)

As for 102(g) prior invention defenses, once a challenger (Merck) of a patent has established prior invention by clear and convincing evidence, the burden of proof shifts to the patentee (Apotex) to produce evidence sufficient to create a genuine issue of material fact as to whether the prior inventor has suppressed or concealed the invention. Once the patentee has satisfied its burden of production, the challenger must rebut any alleged suppression or concealment with clear and convincing evidence.