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STATE AGs URGED NOT TO PUNISH FIRMS FOR ASSERTING PATENT RIGHTS

(In re: Buspirone Patent Litigation)

The Washington Legal Foundation (WLF) this week urged state attorneys general in California, Florida, Massachusetts, and Texas to ignore a request from an activist senior citizens group that they take action against a pharmaceutical company for aggressively defending its patent rights to a popular anti-anxiety medication.

In letters addressed to those attorney generals, WLF argued that pharmaceutical companies act totally appropriately when they seek to protect their intellectual property rights, and that action by state governments against companies for taking such measures could slow development of life-saving therapies for patients. WLF explained that state enforcement actions would tend to undermine the incentives that federal law has provided to drug researchers to develop new therapies.

WLF's letters were in response to a series of letters sent to the four state attorneys general by SPAN, an activist senior citizen group that lobbies for reduction in drug prices. SPAN argued that Bristol-Myers Squibb (BMS), a large pharmaceutical company, had violated state antitrust and unfair trade practices laws when it sought to defend its patents involving buspirone (an anti-anxiety medication marketed by BMS under the brand name BuSpar). BMS's initial patent for buspirone expired in November 2000. However, BMS also held an unexpired method-of-use patent for treating anxiety with a metabolite known as BMY 28764. Because the human body breaks down buspirone into BMY 28764 and the latter is the chemical agent that actually reduces anxiety, BMS argued before FDA in late 2000 that its second patent precluded the marketing of buspirone by generic manufacturers (who were poised to begin such marketing after the November 2000 expiration of the initial patent). FDA determined that the judiciary, rather than FDA, was the proper forum for resolving this patent dispute, and thus it declined to grant the generic manufacturers' applications to market buspirone.

Generic manufacturers thereafter filed suits against FDA and BMS, asserting that their marketing applications should be granted because they could market buspirone without infringing BMS's method-of-use patent. A federal district court in Baltimore upheld FDA's position, but in mid-March a district court in Washington, D.C. granted a preliminary injunction requiring FDA to approve the marketing of buspirone by generic manufacturers. The Washington, D.C. court held that BMS's method-of-use patent would not be infringed by such marketing. BMS has appealed that decision; in the meantime, FDA has approved one generic manufacturer's application to begin immediate marketing of buspirone.

In its letters to the four attorneys general, SPAN noted that consumer prices tend to drop considerably after generic production of a prescription drug has begun, thus forcing the "pioneer" manufacturer to compete on the basis of price. SPAN argued that but for BMS's actions, price competition in buspirone sales would have begun four months earlier -- in November 2000 instead of March 2001. SPAN asked the attorneys general to file suit against BMS on behalf of their states' consumers, in order to recover the "excess" prices paid for buspirone during that four-month period.

In its letters, WLF argued that there can be no justification for such actions against BMS. WLF argued that BMS is well within its rights in vigorously defending its patent rights before FDA and the federal courts. WLF noted that -- contrary to statements from SPAN -- the district judge that ruled against BMS and FDA never stated that BMS had misled either FDA or the Patent and Trademark Office with respect to its patent claims.

WLF also argued that discouraging patent holders such as BMS from vigorously protecting their patent rights would slow development of life-saving therapies. WLF argued that American leadership in developing such therapies is a direct result of the U.S. policy of permitting pharmaceutical companies that gamble the substantial sums necessary for development of new therapies to reap substantial rewards when their research and development expenditures bear fruit. But American companies will not continue to make those substantial expenditures in the absence of assurances that they will be granted exclusive rights to market their new therapies for a reasonable period of time, WLF argued. WLF stated that because of the substantial lag time between a drug company's receipt of a patent for a new drug and the date on which it receives FDA approval to begin marketing, companies rarely receive anywhere near the 17 years of exclusivity promised under the patent laws. Under those circumstances, drug companies should not be penalized for efforts to extend their exclusivity period even when (as the district court in Washington, D.C. held in this case) the company's legal arguments were not persuasive.

WLF is a public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government.

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