Hearings that the Federal Trade Commission (FTC) and the Justice Department are quietly holding around the country raise the possibility that the FTC’s limited (until now) skirmishes with brand-name drug companies might flare up into a broader war. The FTC and Justice are taking the temperature of various high-tech industries to determine whether federal policy on patents needs to be changed. Executives from the software, computer, telecommunications, and drug industries have all testified.

But when it comes to the enforcement of laws related to patents, the FTC has been tougher on the drug industry than any other. The FTC has filed a number of enforcement actions over the past few years against companies such as Abbott Laboratories, Hoechst Marion Roussel (now Aventis), and Schering-Plough, charging that the brand-name companies colluded with generic companies to extend the patent life of brand-name drugs. The FTC and Justice are particularly concerned about the finagling over the drug patents, because within the next five years, patents on brand-name drugs (which have combined U.S. sales approaching $20 billion) will expire.

In the three enforcement actions mentioned above, the FTC alleged that each of the three companies had colluded, using provisions of the 1984 Hatch-Waxman Act, to keep generic replacements off the market even though the patents for the “pioneer” drugs, as the FDA calls them, had expired or were about to expire. For example, a brand-name company can tack an extra 30 months onto the life of its patent by claiming the generic company would be infringing on its patent. To save themselves money and time, the brand-name companies sometimes strike a deal with generic companies. In Abbott’s case, for example, the FTC argued that Abbott paid Geneva approximately $4.5 million per month to keep Geneva’s generic version of Abbott’s proprietary drug (Hytrin) off the U.S. market, potentially costing consumers hundreds of millions of dollars a year. Hytrin is used to treat hypertension and benign prostatic hyperplasia (BPH or enlarged prostate)—chronic conditions that affect millions of Americans each year. Abbott projected that Geneva’s entry with a generic version of Hytrin would eliminate over $185 million in Hytrin sales in just six months.

These three cases piqued the FTC’s suspicions; so in April 2001, it issued information requests to about 75 patent-focused and generic drug companies seeking information about patent collusion. The FTC has that information in-house now, and is examining it; it was supposed to have published a report at the end of 2001. But that is still in progress, and might in fact be influenced by the national hearings that the agency has been holding.

Not only have the FTC enforcement actions given way to national patent policy hearings, they have stimulated political pressure, too. At the end of February, a group calling itself Business for Affordable Medicine (BAM) held dueling press conferences with the Pharmaceutical Research and Manufacturers of America (PhRMA), the drug manufacturers’ trade association. BAM is composed of the governors of Alabama, Hawaii, Louisiana, Missouri, New Hampshire, Vermont, Washington, and West Virginia, along with employers such as GM, Georgia Pacific and Kodak, and the Ohio and Utah state chapters of the AFL-CIO—a potent brew. BAM said states could save $600 million over the next three years if Congress acts to tighten the Hatch-Waxman Act. PhRMA wasn’t too excited about the idea. “It would be a devastating blow to America’s patients,” said Richard Smith, vice president of policy for PhRMA.

There have been a couple of bills kicking around in Congress that would make changes in Hatch-Waxman. A major reform proposal from Senator Charles Schumer (D-NY) has little chance of moving forward any time soon. But Senator Pat Leahy (D-VT) has a bill that is more of a compromise—it would simply require brand-name companies to immediately make public any deal they make with a generic company that involves delaying a generic application for a drug whose patent is up. Senator Orrin Hatch (R-Utah), the top Republican on the Judiciary Committee, which Leahy chairs, says that concept is one of “great merit.”

Of course, passage of the Leahy bill would be like waving a red scarf in front of a bull called FTC.