



Daniel J. Popeo: FTC's anti-consumer crusade on drug patent litigation

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August 19, 2010

When it comes to Washington decision-making, the media, and in turn, the American public, devotes most if not all of its attention to Congress and the president. Such a focus regrettably distracts most Americans from the critical, and often economically destructive, work of federal regulatory agencies.

Anti-business activism at EPA, FDA, and the Department of Justice has received some scrutiny, but the lower-profile efforts of other powerful regulators remains far under the radar.

Consider, for instance, the Federal Trade Commission's (FTC) irrational crusade against settlements of patent litigation between branded pharmaceutical companies and generic drug makers.

The FTC's position on these settlements, which can bring generics to the market faster and lower health care costs for sick patients and government purchasers, is hostile to medical consumers. Even worse, the commission has resorted to highly questionable use of its enforcement authority to advance this counterproductive agenda.

Some background on patent litigation and settlements is necessary. Patents provide inventors of drugs with a temporary exclusive property right so they can recover their enormous research and development investments.

A 1984 federal law empowered generic drug makers to challenge the validity of a drug patent before the patent term expired. If the generic company prevailed, it could immediately release its drug and would enjoy a 180 day period of exclusive access to the generic market.

Such litigation can cost millions of dollars and keep the generic drug off the market for years. The branded and generic companies often settle such litigation, and on occasion, such settlements include a payment of money to the generic company and an agreed timetable for the generic drug's release.

The FTC has labeled such settlements "pay-for-delay," and has argued in court for the past 10 years that they are inherently anti-competitive. "Pay-for-delay" may be a catchy phrase, but it is an entirely inapt one.

In each instance where the FTC has challenged a patent litigation settlement, the settlement resulted in no delay. In fact, they allowed the generic drug to enter the market *before* the branded patent expired, providing consumers with faster access to cheaper generic drugs.

The FTC's view has never prevailed in court. The commission has also unsuccessfully pushed Congress to ban such settlements. Finding roadblocks in the courts and Congress, the FTC has pursued its anti-settlement agenda through aggressive use of its considerable regulatory power.

The commission's actions have recently led to a heated court battle where a generic company accused the FTC of abusing its authority. Last year, the FTC learned that generic company Watson Pharmaceutical had filed a request with FDA to copy a patent-protected narcolepsy drug called Provigil.

The FTC also learned that Watson likely possessed the exclusive right to market such a generic for 180 days, and was concerned that Watson would seek an agreement with Provigil's inventor to "delay" the generic's release.

Seemingly motivated by this fear, the FTC took the remarkable step of contacting one of Watson's competitors, Apotex, to see if it would purchase Watson's exclusive rights to generic Provigil.

Next, a senior FTC official contacted Watson's outside counsel to suggest that Watson respond positively to Apotex. The same Watson attorney testified that the FTC official also told him the company's refusal to sell its rights could cause "the FTC 'front office' to initiate an investigation." Watson decided to retain its exclusive rights, and rejected Apotex's offer.

The FTC saw this as proof that Watson would make a pay-for-delay deal with Provigil's producer, Cephalon. Even though Watson's general counsel formally testified to the FTC that Watson had no contact with Cephalon, the commission subpoenaed Watson's CEO seeking his testimony on the matter.

Watson opposed the subpoena, arguing among other things that the FTC was acting beyond its statutory authority and that it issued the subpoena for the “improper purpose” of forcing Watson into a bad business deal.

The judge presiding over the case ordered FTC officials to answer formal questions posed by Watson’s counsel. The answers Watson received confirmed that if Watson had sold its generic exclusivity rights to Apotex, the FTC never would have pursued its investigation or subpoenaed Watson’s CEO.

This past Tuesday, the court regrettably upheld enforcement of the FTC’s subpoena. The judge professed his “disagreement” with some of the FTC’s actions, particularly its use of its investigatory power to advance a preferred business deal.

But the judge ultimately deferred to the FTC, ruling that Watson did not meet the impossibly high burden of proving that FTC had absolutely *no* proper purpose for issuing its subpoena.

While the court’s commentary on the “questionable” nature of the FTC’s actions are welcome, they are no substitute for the type of judicial oversight that targets of powerful federal agencies need.

If Watson does appeal, let’s hope higher courts do more to protect the company’s rights. More importantly, someone, be it Congress or the FTC’s inspector general, needs to hold the commission accountable for its abusive actions.

Failure to do so sends a dangerous message to all federal bureaucrats: When imposing your regulatory agendas on free enterprise, just about anything goes.

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