Response of Michael Wroblewski to Questions Submitted by Senator Dianne Feinstein Following the January 17, 2007 Senate Judiciary Committee Hearing: "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?"

Question: The Eleventh Circuit held in the *Schering-Plough* case that there was no antitrust violation when a settlement between a name-brand pharmaceutical company and a generic manufacturer prevented the generic company from marketing the competing generic product – because the settlement did not stifle any competition beyond what the patent already prohibited. To reach this conclusion, the court relied on a presumption that patents are valid.

> • *To reach a conclusion that such a settlement is inherently anticompetitive, do we have to assume that the patent is* ***not*** *valid?*

Answer: No. It is unnecessary for the plaintiff to offer proof on the underlying merits of the patent dispute, in order to establish whether the agreement is illegal. *Tamoxifen Citrate Antitrust Litigation*, 429 F.3d 370, 388 (2d. Cir. 2005). In determining whether an agreement is unlawful (and not whether there is consumer harm), courts must assess the agreement at the time it was made to determine whether it was "unreasonable," *i.e.*, whether it likely delayed generic entry beyond the date that would have been provided in a differently crafted settlement. The law distinguishes between a determination of whether an agreement is anticompetitive and whether consumers have been harmed by the agreement after the fact. It is in this latter determination in which patent validity or infringement would be at issue.

In the *Tamoxifen* case, the court dismissed an antitrust challenge to an agreement that settled a patent dispute between a brand and generic company, with terms that included a reverse payment from the brand to the generic company. In return, the generic company agreed not to market its own version of the Tamoxifen drug prior to the expiration of the patent, but instead took a license to sell product manufactured by the pioneer. In that case, however, the validity of the brand company's patent was the crucial issue in the underlying patent dispute and, subsequent to the settlement in question, the brand company's patent was successfully defended in litigation with three other generic challengers. In a private action for damages, after the fact, the *Tamoxifen* court had good reason to believe that the settlement did not ultimately cause consumer harm.

The simple logic behind distinguishing between legality and damages can be illustrated in another context. If, for example, a firm entered into an agreement with a would-be new entrant in which the new entrant agreed to delay or forgo introduction of its new product, it would be no defense for the firm already in the market to argue that the new product *might* not have succeeded in the market. Similarly, the existence of such uncertainties cannot justify an agreement whose very purpose is to ensure against an increase in competition, by guaranteeing that the new product will not be introduced.

• *If yes, why should we start from an assumption that the patent in question is not valid?*

Answer:

Not applicable, see answer above.

Response of Michael Wroblewski, Consumers Union to Senator Kohl's Follow-up Questions from Hearing on "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?"

Question 1: Do you have an estimate of how much consumers are paying as a result of these "reverse payment" patent settlements which have the effect of keeping generic competition off the market?

Answer: Consumers Union does not have a dollar amount of consumer harm because of these "reverse payment" settlements because identity of the drug products is not publicly known.

Consumer Reports has estimated that individual consumers can save hundreds of dollars per year if they fill their prescriptions with generic drugs for just one class of drugs. For example, consumers who need medicine to lower their cholesterol could save up to $1,800 per year.[1] This amount varies depending upon the identity and number of prescription drugs a consumer takes.

Question 2: In your view, are there any circumstances in which consumers are benefited by a patent settlement in which a generic firm agrees to keep its drug off the market in return for a cash payment from a brand name manufacturer?

Answer: No, I can think of almost no circumstances in which in the long run consumers benefit from these payments. If Congress believes that there are such circumstances, the legislation could be amended so that the settling parties could petition the FTC for approval of patent settlement agreements containing reverse payments.

Brand and generic companies argue that settlements with reverse payments permit generic entry prior to patent expiration, in some cases several years in advance of patent expiration. *See* Testimony of Bruce L. Downey at 2, Senate Committee on the Judiciary Hearing, "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?" (Jan. 17, 2007). I believe two reasons undermine this argument.

First, absent the reverse payment, the parties could find another basis on which to settle the case. For example, depending upon the strength of the patent, the parties could negotiate an earlier generic entry date (*i.e.*, a brand company with a weak patent case may be willing to negotiate an earlier entry date than it would if it also made a reverse payment to the generic company). Indeed, the FTC data for FY 2004 and 2005 (when it was thought to be illegal to use reverse payments) showed that brand and generic companies found ways to settle patent litigation, just not with a reverse payment.

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[1] "New Generic Statins Mean Big Savings for Consumers Needing Cholesterol Reduction, Consumers Union Best Buy Drugs (June 22, 2006), available at http://www.consumersunion.org/pub/core_health_care/003557.html.

Second, if the brand and generic companies cannot agree on a settlement without a reverse payment, the public interest in speeding market entry for generic drugs favors a court decision in the patent litigation case. The FTC 2002 Generic Drug Study shows that generic companies won 73% of their patent challenges in those cases in which a court ruled on patent validity or infringement. Even if the generic success rate were lower (*e.g.*, 50%), generic entry is likely to occur earlier than when the brand and generic companies privately decide when generic entry should occur.

Question 3: The FTC reports that in the year after the two court decisions allowing these "reverse payment" patent settlements, half of all patent settlements contained terms in which the brand name company paid the generic money in return for the generic's agreement to keep its drug off the market. The year before the court decision, no patent settlements contained such terms. Doesn't this data show that such "reverse payment" settlements are likely to become increasingly common unless our legislation is enacted?

Answer: Yes, the FTC's FY 2006 data show that unless your legislation is enacted, there will continue to be settlements that keep generic drugs off the market. Indeed, the FTC's recent data shows history repeating itself. Prior to the FTC's legal challenges to these types of agreements, there were a substantial number of agreements with reverse payments. The FTC's 2002 Generic Drug Study showed that of the 20 final settlements between brand name and generic companies between 1992 and 2002, nine contained reverse payments. FTC Generic Drug Study at 28 (Table 3-1). The delay of generic entry ranged from 4 months to 10 years. The 9 brand-name drugs subject to these agreements had annual sales, in the year the agreement was made, that ranged from less than $100 million to over $1 billion. As your question notes, these types of agreements have reappeared.