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Addressing Reverse Settlement Problem through Patent Law

Over the last few years a new phenomenon emerged in litigation over patents covering pharmaceutical products. This phenomenon would pass largely unnoticed in most other litigation contexts, but in the very specific world of pharmaceutical patent litigation it raised more than a few eyebrows. Indeed, it raised the ire of at least one U.S. Court of Appeals, the Federal Trade Commission, and numerous Senators and Congressmen, as well as spawned a fair amount of academic commentary. The phenomenon I am talking about is settlements between the patent holders and the generic companies challenging the patents. The wrinkle is that unlike most settlements where the alleged trespasser on someone else’s rights settles with that person in order to avoid litigation, in these settlements, it is the rights holder that pays the alleged trespasser. For these reasons these settlements have been termed “pay to delay settlements,” “reverse payment settlements” or simply “reverse settlements.”

Those who perceive these types of settlements to be a nefarious plot by patent holders to continue unwarranted market exclusivity have focused their energy on using the antitrust laws to curtail these activities. The reasoning is that by entering into settlement agreements, patent holders prevent generic manufacturers from entering the market thus raising costs for consumers. This logic is of course predicated on the supposition that absent settlement, generics would be able to enter the market. That, however, is far from certain. After all, in these cases, the brand name drug manufacturers hold a patent that precludes others from making, using, or selling the patented technology, and that absent a conclusive judicial determination such patents remain valid. For this reason, three of the four Courts of Appeals faced with reverse settlements have rejected the antitrust position advanced by the Federal Trade Commission. The fundamental problem with the FTC’s approach is inherent and constant tension between antitrust law and patent law. Whereas the former seeks to enhance competition by restricting monopolies, the latter seeks to promote competition by granting temporally limited monopolies.

Instead of attempting to fit a square peg of patent problem into a round hole of antitrust law, this Article proposed a different solution that will not unduly discourage settlements, have due regard for competition, and is in line with the original purposes of the Hatch-Waxman Act. The Hatch-Waxman Act sought to promote competition in pharmaceutical products by incentivising generic manufacturers to challenge weak patents and have courts declare these patents to be invalid or unenforceable. Clearing the commons of invalid patents would then spur competition. The Act, however, foresaw that not all of the challenged patents would be declared invalid. This means that settling litigation where a patent is properly issued serves the purposes of patent law, while settling litigation where the patent would have been declared invalid frustrates both goals of the Hatch-Waxman Act (increased competition and “clearing the commons.”) Addressing the problem through antitrust law at best resolves the competition problem, but does little to clear the commons of worthless and improperly issued patents. Instead, the problem should be addressed through patent law itself.

The U.S. Patent and Trademark Office has the authority to order reexamination of any patent at any time there arises a “substantial new question of patentability.” The Patent Act permits “[a]ny person at any time [to] file a request for reexamination by the Office of any claim of a patent on the basis of any prior art . . . .” The Act does not limit submissions to newly discovered prior art. Rather, the person making the submission has to identify for the Patent Office why the identified prior art is relevant and how it casts a “substantial new question of patentability” on the issued patent. This is true even if the PTO has previously considered the art. Additionally, the current version of the Hatch-Waxman Act requires that any generic challenging the validity of a patent under the provisions of the Act provide opinion of counsel identifying the basis for such a challenge to the patentee and the FDA. Finally, the Hatch-Waxman Act
requires all parties to a reverse settlement to submit a copy of the settlement to the FTC. Combining these two statutory mechanisms, it is possible to police reverse settlements through patent law.

Reverse settlements should be treated as a signal to the Patent Office that private parties (the patentee and the generic challenger) have some doubts about the strength of the patent at issue. The size of the settlement would indicate whether the doubts are “substantial,” in other words whether there exists in the mind of the parties a “substantial new question of patentability” of the patent in suit. As the settlements get larger, the question of patentability can be viewed to be more and more substantial, and at some point should trigger a reexamination of the patent. If the present law is minimally amended, to require not only that opinion of counsel be shared with the patentee and the FDA, but also be filed with the FTC whenever a copy of any reverse settlement agreement is filed, the FTC could then examine the size of the settlement and if need be refer the patent to the PTO for a reexamination. Because the PTO would be in possession of a considered legal opinion identifying potential bases for invalidity, it could proceed to determine whether the identified basis present a “substantial new question” of patentability, and if so proceed to reexamine the patent.

One of the fundamental advantages of the proposed approach is that it does not depend on adversarial litigation or any particular party challenging a patent. Because the PTO conducts its reexamination ex parte upon either its own motion or following a submission from “any person,” the patentee cannot possibly contract away this procedure, unlike the judicial inquiry. Consequently, it would be impossible for the patentee and the generic challenger to collude in order to keep an invalid patent on the market while splitting the supra-competitive profits. The second advantage is that the proposed system closely tracks the goals of the Hatch-Waxman Act. Should the PTO determine that the patent was properly issued it would necessarily follow that the settlement was proper, for the exclusion of the generic would not be the result of an illegal payment, but the result of the scope of a now-confirmed valid patent. Alternatively, should the PTO reject the claims, thus removing the patentee’s ability to enforce a now-non-existent patent, the market would become open to any other generic manufacturer who wishes to enter it. All that would need to be done is for that manufacturer to file an Abbreviated New Drug Application certifying that no valid patent covering the drug in question exists. Assuming that the generic would be able to satisfy the bioequivalence requirements, nothing would stand in the way of FDA approving the generic version and that version entering the market to the benefit of consumers. By approaching what is ultimately a patent problem with the proper tools of patent law rather than ill-fitting instruments of antitrust law, we could simultaneously serve the goals of the Hatch-Waxman Act, remove the guess work inherent in post hoc evaluations of patents’ strengths or parties’ ex ante expectations, and promote competition and consumer access to lower cost medications.