Product hopping: Legal or not?

Big pharma finds way to delay competition, but is it acceptable?

BY BRETT JOHNSON

W hen legal conundrums manifest in the arena of pharmaceuticals, they haunt it for decades. Take the industry’s long-headline-dominating “pay-for-delay” cases; Richard Hernandez of McCarter & English just got word that a case of his involving that issue would be moving into a new phase.

... After pending in the courts since its 1999 filing.

And the specter that is the next generation of legal questions, which may reappear just as long from now, is already taking shape.

These questions involve the standing of “product hopping,” or a brand name drug company’s updating drugs with soon-to-expire patents to give itself a new patented product that, for some time, has no generic equivalent. That allows the company to avoid automatic substitution to the cheaper products of generic competitors.

Like “pay-for-delay,” which dealt with branded companies paying to keep rivaling generic products off the market for a set amount of time, it’s at the intersection of patent and antitrust law.

“... And depending on where the courts come down on the issue, the implications are wide,” said Hernandez, who represents branded drug companies. “There are lots of drugs out there for which (product hopping) has occurred.

“There’s potential liability across the entire industry.”

Though the implications are sure, the future of it in the courts isn’t.

“Product hopping is a complex issue,” said Michael Carrier, a Rutgers School of Law professor. “On one hand, the (brand-ed) pharmaceutical company has earned a patent and can argue that it’s pushing innovation; but, on the other hand, it might simply be their attempt to hurt generic competition.”

And, he clarified, the legal framework has not been established for the purpose of rewarding a branded pharmaceutical company for innovation. The emphasis is instead on lowering prices of prescription pills for patients, which access to generics allows. Generic drugs can be up to 90 percent cheaper than brand names, according to Medical Daily.

Carrier pointed to 1984’s landmark Hatch-Waxman Act, which explicitly supports the role generic drug companies play by increasing the market accessibility of these off-brand products.

When a doctor writes a prescription, it’s almost never for a generic drug. But at the pharmacy level, many states mandate that the cheapest medication be substituted for the more expensive branded form.

Even in states where this substitution is required, that swap is dependent on the branded drug on the patient’s prescription having an available generic alternative.

“... When branded companies are the only option on the market for a particular product, they can charge what people refer to as monopoly prices,” Hernandez said. “And they have the patent right to do that.”

He further explained that a big pharmaceutical company charges as much as it does for branded pills because it has to spend decades doing research and development and clinical studies, while generic drug companies just need to copy the formula and demonstrate its same effects.

“A branded pharmaceutical company spends literally billions of dollars in R&D,” Hernandez said. “Generics just have to spend money to actually duplicate the pill, which is a much easier and less expensive process.

“The minute that a generic enters the market, the price drops 50 percent, if not more. What will happen is, when the second generic comes in, it drops again. It very quickly goes from a blockbuster, profiting drug to a commodity.”

So, in order to preserve its bottom line, the branded drug company will engage in so-called product hopping, perhaps sending its promotional force out in number to get doctors to transition.

“It makes a huge difference in price for the consumer when there’s no generic,” Carrier said. “It’s a unique industry in that the payer is not the decision maker. The doctor might prescribe the new drug just because he receives all the promotion and marketing from the drug company.”
Another concern with product hopping is how rarely these adjustments seem like significant innovation, Carrier added. A branded drug company’s changes can run the gamut: from scoring the pill so it can be split in half, to upping the dosage to just turning a capsule into a tablet.

Hernandez said the branded companies will argue that it provides the doctor with more flexibility. He added that, for innovation’s sake, the industry shouldn’t curb improvements to medication, however incremental.

Courts are going to be skeptical about the innovation argument when the decision to improve is being made on the eve of patent expirations, Seton Hall School of Law professor Jordan Paradise said.

It boils down to three questions for Hernandez: Is the court in a position to decide what’s enough innovation to allow competition to be restricted? What’s the test? Does a branded company have to apologize for wanting to make money off its innovation?

The initial, barest hints of an answer from the court on these questions favored his side. Hernandez, an antitrust litigator, and Jonathan Short, a patent litigator, teamed up to represent Mayne Pharmaceuticals in a product hopping case tied to its acne medication. Theirs marked the first case to go through the process and reach a summary judgment.

A federal judge from the Eastern District of Pennsylvania last month ruled that their client did not engage in illegal anti-competitive behavior, even if its move to a new product kept generic versions off the market for a longer time period.

“One of the key findings was that the drug was not the only way to treat acne,” Short said. “There are lots of drugs that can do that and substitutes available.... For it to be considered a monopoly, you have to have something north of 60 percent of the market. We had something like 18 percent of the market because it was defined as oral antibiotic.”

Nearly simultaneously, courts were favoring the generic side — and, because of the lower prices of generics, the consumer side — in another product hopping dispute.

Late last month, a U.S. Court of Appeals Second Circuit decision upheld the New York attorney general’s preliminary injunction in a case against Actavis’ Forest Laboratories LLC and its plans for its Alzheimer’s treatment.

The injunction forced Forest to restart manufacturing of the old version of its Namenda medication, which was changed from a twice-daily pill to a once-a-day slow release version. The company originally said it would discontinue the older drug in August, then it said the patient would have to take extra steps to get it.

This is what is referred to as a “hard switch” — when a drug company pulls the older pill off the market in favor of its new product, for which there is no generic available.

“So doctors can’t prescribe it even if they want to,” Hernandez said. “Sometimes the company will go out and buy out all the inventory the pharmacies have in connection with that.”

A “soft switch,” as Hernandez’s client did, is when a company converts enough doctors to prescribing the new drug, but leaves the old version untouched on the shelves.

The Forest case and the Mayne case still have the potential to go different directions in higher courts, but the former has so far been a win for generics, and the latter for branded companies.

“What these two cases show is that the facts of these cases matter a lot,” Carrier said. “The cases seem to focus on one factor: whether customers are being coerced to accept a new product. Improving products or innovating is not violating an antitrust law. (Forcefully) extending a monopoly is.”

As with the pay-for-delay cases, product hopping cases might come to a Supreme Court decision, which is sought upon a circuit split.

Expect more Garden State headlines in the meantime.

“Given that New Jersey is the so-called ‘medicine chest of the world,’ this is going to be important to watch,” Short said. E-mail to: brett@njbiz.com On Twitter: @reporterbrett

What’s the prescription?
Early as it is into what could be a protracted legal skirmish, McCarter & English attorney Richard Hernandez has been assailed with uncertainty.

“Do I tell a client not to write in any document that you’re (product hopping) to keep competitors off the market when you have an old drug coming off patent, even though that’s what you’re doing?”

The cost of being wrong is tremendous. And it’s hard for him to tell what behavior will ultimately be acceptable to the courts.

But there’s one thing he is certain of: “What we’re telling clients today is to not pull their old drug entirely off the market or make it impossible to get. The law seems to be that hard switches aren’t OK, and soft are.

“And that advice is subject to what happens tomorrow, or in the next case.”