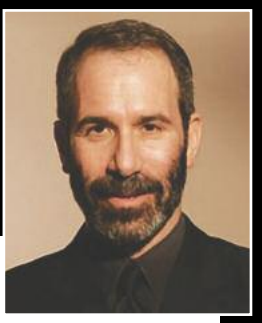

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Contributed by Gil Bashe

REVERSE-PAYMENTS BELTWAY BAN DROPPED, BUT NOT FORGOTTEN

Reputation malaise has made the U.S.-based pharmaceutical industry vulnerable to "Beltway advocacy." Science has lost its life-enhancing societal mystique and at risk is its intellectual property. Drug-discovery successes and the stellar reputation of the 1980s and 1990s — driving breakthrough treatments for AIDS, cancers, heart disease, and even once-considered deadly rare disorders — occur in waves of industry-inspired effort. But breakthroughs of the past may not be repeated if innovation is not championed through intellectual property protection.

Now, an industry seeking to guard its intellectual property, much like any business sector — from music to technology — is attacked as limiting fair competition. What is at stake is the right environment needed for innovation to impact worldwide human health. While the Federal Trade Commission and a few members of Congress believe patent-litigation settlements that include reverse-payment provisions (labeled by critics as "pay-for-delay") cost the public by delaying generic market entry, pulling the plug on the ability to resolve patent litigation may ultimately threaten innovation.

Major generic companies such as Barr and Teva have long used patent challenges as avenues to gain early access to successful medicines, introduce them into the marketplace sooner, recover costs associated with legal fees, and reap a slice of the sales revenue. However, when it comes to launching a generic-at-risk patent litigation there are no guarantees. Sometimes these cases pay off and other times they don't. When the innovator sues the generic company for violating its patent, the innovator often wins its suit. But litigating is expensive, time-consuming, and uncertain; settling out of court provides both parties with certainty and stability, two factors necessary for creating an environment that fosters innovation. Patent settlements also do more than guarantee early entry of patent-protected brand products onto the generic scene; they may actually save taxpayer resources while directing those dollars that might have been squandered in legal fees toward the future of clinical innovation.

REALITY SHOWS ASSERTIONS ARE NOT FACTS

The crux of the FTC argument for banning patent settlements was articulated in its January 2010 report claiming these settlements "deprive consumers of lower-cost drugs to the tune of $3.5 billion each year." The suggested cost-savings in the report received wide media attention and caused a Capitol Hill stir. But are they true? In the report, the FTC stated that 73% of these generic-company patent challenges would result in a loss of patent if they had gone to trial, thus saving Americans billions. However, there are no third-party statistics to validate these statements and no crystal ball to determine potential verdicts. In fact, the FTC acknowledges that its estimates are based on self-imposed assumptions. Others say the actual win-ratio for patent disputes would be closer to 48%.

Additionally, many of the references contained within the FTC report, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," are the remarks of Commissioner Jon Leibowitz in public fora — not in-depth, unbiased academic analyses. When people move from the report "call-outs" to the back-of-the-booklet data references, they will find little validated information. For example, FTC asserts that generic prices are as much as 90% less expensive than brands. Like its projected annual savings (FTC low-range savings never stated in public is $600 million), the highest range for brand/generic price differences is positioned. In fact, the Generics Pharmaceutical Association (GPhA) says the "average retail price for a brand drug was $96.01 while the average retail price of a generic was $28.74, a savings of nearly 70% per prescription."

According to GPhA former President and CEO Kathleen Jaeger, "Over the past 20 years, generic manufacturers have undertaken numerous patent challenges, prompted by the 180-day exclusivity incentive under Hatch-Waxman. Successful patent challenges have generated tens of billions of dollars in savings for American consumers and only a small number have involved litigation settlements between the brand and generic companies. An outright ban on settlements as a means of resolving patent litigation would stifle competition from generics, denying patients access to affordable medicines and reducing overall cost-savings from generics."

GPhA claims and the flaws in the FTC economic-savings assertions are well-demonstrated. One recent patent challenge example shows how easily the suggested saving evaporates when forced litigation is the only route for resolution: the Apotex-Bristol Myers Squibb (BMS) patent battle surrounding Plavix.

Plavix annual U.S. sales are reported to top $3 billion. Had the FTC allowed the Apotex-BMS patent-dispute settlement to stand, Plavix would now be a generic product. Forcing resolution through litigation resulted in BMS defending its patent position and, eventually, winning the protracted court case. The price-tag for this "to-the-bitter-end" litigation is usually very high, often close to $100 million. This is money that might have been directed toward other endeavors, such as research. And what of the price tag to the 5 million Americans using Plavix who will now have to wait until the patent expires for a generic to be available? The FTC position against patent settlements cost the health system millions of dollars that might have been saved. As this high-profile example illustrates, banning patent settlements can result in the saving promised to taxpayers vanishing.

PHARMA INNOVATION AT RISK

Another potentially even more significant problem with the FTC position regarding banning patent settlements is the role of these settlements in safeguarding pharmaceutical innovation. No longer is the future of breakthrough medicines derived from the labs of mega-pharmaceutical companies. Rather the new source of life-saving medicines will spring forth from midsized biopharma companies. And these companies need to be protected.

Pfizer's Chief of Worldwide Research Robert MacKenzie, Ph.D., summarized this idea best when he noted recently that the traditional pharma R&D strategy creates a system steeped in bureaucracy and lacking in accountability.

"We believe that the big research organization model really doesn't work particularly well," Dr. MacKenzie said. "Pfizer is steadily reorganizing its R&D model to reflect the organizational model of smaller companies. Many large companies are using their stock-value cash position to acquire entrepreneurial companies to refill dry pipelines."

Innovation is not only the product of brilliant minds; a clear regulatory process and the direction of Hatch-Waxman legislation are needed. More than ever, private-equity investment is fueling the future of innovation. All of the entrepreneurial spirit in the world, backed by great scientific genius, cannot bring a product from lab bench to bedside without investment. The reality is stark. Chicago Tribune's Bruce Japsen, reporting from this year's annual Biotechnology Industry Organization's meeting, writes: "The banking crisis that has tightened lending and made investors skittish about risky propositions, including biotechnology, has led to a 25% decline in publicly traded biotech companies."

Now add to that risk concern for intellectual property protection and capital will dry up quickly.

FIGHT OR FOLD

But what happens if patent settlements are overturned, restricted, or even banned? The economics of healthcare discovery will change rapidly. Deep-pocket generic companies, such as Barr and Teva, will suddenly pick-and-choose their patent-challenge cases cautiously. No longer will the threat of potentially losing a court decision force innovators to come to the table and settle and, as a result, guarantee that patent-protected innovations enter the generic market earlier as "authorized generics." Suddenly, innovators will have two choices: fight in court or fold.

For large pharmaceutical companies, litigation will be an expensive but necessary choice to guard their intellectual property. A ban on settlements would encourage patent violation, particularly of medicines developed by companies with limited resources to initiate litigation. The smaller innovator companies will have to determine risk/benefit tolerance of protecting a patent in court or pursuing the possible benefits of a new molecule. More likely, they will be forced to sell themselves on the cheap to bigger pharmaceutical companies with deeper pockets for litigation. In that case, shareholders are shortchanged on the value created.

CONSTITUTIONAL RIGHTS

If patent settlements are banned, fewer large generic companies will head toward the courts, and when they do, they will target the shallower pockets of smaller pharma innovators that are leading the charge with newer medical advances, knowing these companies may not have the resources to defend their patents. Ultimately, this might dangerously affect the innovative abilities of smaller companies.

The Constitution makes it clear in Article I, Section 8: "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." A few people in the Beltway might want to re-read this guiding framework and resist from tampering with the patents.

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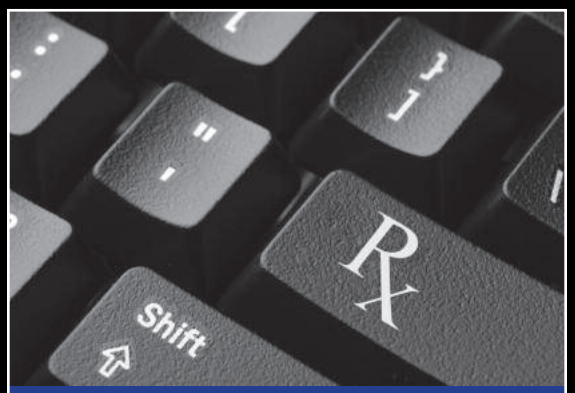

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