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Upsetting the Balance in Prescription Drugs

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Of all the laws on the books, few have greater support than recordation statutes and statutes of limitations. When applied properly, they facilitate the acquisition and sale of property and provide a stable mechanism for resolving disputes. Both are instrumental to a growing and prosperous economy.

However, when misapplied, these laws can wreck havoc on an economy, discourage innovation and create a litigation morass — as the U.S. Senate will discover if it continues down a path on which it recently embarked.

The Benefits of Recordation Statutes. Recordation statutes require property holders to list their claims to property in a public registry, which gives notice of their holdings to the public-at-large. Recordation thus supplies a secure institutional framework that allows property to be freely bought and sold. Without recordation it would be very difficult for a buyer to know if a seller has a clear title to the property he purports to sell.

The Benefits of Statutes of Limitations. Statutes of limitations serve a different purpose. While many lawsuits are filed because a plaintiff has been harmed, some lawsuits are gold-digging operations, dragging someone into court for imagined wrongs that occurred many years earlier. Determining who did what to whom can be difficult even when memories are fresh and evidence is available, but it can be almost impossible when memories fade and evidence deteriorates. A statute of limitations instructs everyone to bring a timely suit or forego their claims.

Patents and the Law. Recordation statutes and statutes of limitations work for patents as well as real property by giving fair notice of property claims (in this case, intellectual property) and by encouraging the prompt resolution of legal disputes.

Unfortunately, such socially beneficial laws can be turned to improper social ends. Just that may happen if the novel 30-day registration and 45-day statute of limitations provisions contemplated under the Senate bill known as the "Greater Access to Affordable Pharmaceuticals Act of 2002" (S.812) become law. The proposed legislation is bad patent policy because it covertly undermines current patent protections, which would greatly retard the innovation of new drugs.

In addition, the legislation could deprive a company of the value of its patents without fair compensation, raising serious constitutional issues.

Imposing Re-recordation. Patents, once issued, must be duly registered with the U.S. Patent and Trademark Office. Certain drug patents must be listed a second time in the Food and Drug Administration's (FDA) Orange Book, which covers some patented pharmaceuticals in the various dosages available for sale.

The proposed Senate bill stiffens the Orange Book registration requirements by requiring re-recordation (i.e., recording the same patent more than once). Under the current law, a simple listing of a patent is sufficient. But under the proposed legislation new patents must be recorded *claim by claim* within 30 days after the patent is granted. Existing patents must also be filed claim by claim within 30 days after S.812 becomes law.

This new requirement is no easy task. Complex pharmaceutical patents often contain dozens of separate claims, and most pharmaceutical manufacturers own hundreds of different patents. Re-recordation is, moreover, no simple ministerial act, for scientific judgment is needed to decide whether certain claims are eligible to be filed. The patent holder who errs faces legal sanctions if its listings are not "complete and accurate." But maybe that's the goal. The backers of S.812 seemingly want patent holders to *fail* in their re-recordation efforts so that patented pharmaceuticals will fall into the public domain prior to patent expiration.

Of course, everyone wants more Americans to obtain needed drugs at lower prices, but this legitimate end

does not justify the new burdens imposed by the legislation. After all, the government cannot confiscate private land to build affordable housing for the poor; and it should not be allowed to confiscate the value of a drug company's patent in order to give low-income families access to cheaper pharmaceuticals.

Re-recordation: An Unlikely Mechanism. Such re-recordation schemes are only rarely adopted. Typically, their purpose is to simplify the title to *dormant* mineral interests (e.g. rights to mine coal that have never been used) that have been sold off by a surface owner. These statutes have been sustained in some cases, but struck down in others. The statutes that passed muster all created a statutory grace period of several years, and required the mineral holder to file only a simple form to perfect his dormant claim.

The re-recordation provisions of S.812 do not follow this standard pattern. Today's patented drugs are not dormant, but in active use; title is unified and clear; and no one thinks that the available information on patent scope or product use is inadequate for potential licensees or users. Thus the Senate's bill just creates useless obstacles that serve no public benefit; *its only purpose is to eliminate otherwise valid patents without compensation*. These schemes should surely be struck down when applied to existing patents. And they are likely to reduce the flow of new research innovations.

Finding the Balance on Statutes of Limitations. Everyone agrees that a statute of limitations of one thousand years is too long to be of use.

But it is equally possible to lurch too far in the opposite direction. A statute of limitations that expired one day after the claim accrued would cut off virtually all valid claims and create an open season on private property. Under the guise of regulating the statute of limitations, the legislature has taken property from its owner without compensation.

Some happy medium is needed. In general, the legislature rightly chooses the limitation period. But that legislative discretion is subject to constitutional oversight if the period chosen is so short as to eviscerate the underlying right.

One early 20th century case struck down a statute of limitations that forced a plaintiff who obtained a judgment in one state to sue on it within three months in another state. To be sure, some cases have sustained short statutes of limitations that run between six months and one year. But, invariably, some special purpose justified the use of the short period. Several recent cases, for example, involved title disputes over lands held by various Indian tribes and their members. Short periods of limitation were adopted to permit the quick and orderly resolution of countless titles that had been scrambled through years of disarray and delay. These statutes were sustained because they were not designed to "strip" tribal members of their valid claims, but to encourage quick settlements under a valid congressional process.

Does S.812 Meet the Criteria? No similar justification exists for S.812's statute of limitations because there is no disarray at the patent registry. The result stands even though the 45-day period is drawn from the current Hatch-Waxman Act, where it serves an entirely different function.

Hatch-Waxman helps regulate the transition of drugs from proprietary to a generic status. In exchange for allowing generic manufacturers to experiment with their own versions of a drug while still under patent, the law allows the patent holder, during his patent term, to obtain within 45 days of notice an automatic 30-month stay against a generic manufacturer that claims the patent is invalid or that a drug's manufacture and sale does not infringe upon the proprietary patent.

But note the difference. If a drug manufacturer misses the 45-day deadline provided under Hatch-Waxman, the company still retains its patent and can still sue for patent infringement. Under S.812, an action has to be brought within this short period or the patent would be lost altogether. The backers of S.812 have not offered any justification for this shift. But their motivation appears similar to the bill's re-recordation provisions: *throw the property into the public domain by erecting onerous procedural obstacles to the protection of valid legal claims*. That strategy may make for good politics, but it is makes for bad constitutional law.

Conclusion. The government can take countless steps to reduce the costs of health care. However, confiscation by a hair-trigger statute of limitations and onerous registration provisions should not be among them.

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