# Sen. Orrin Hatch: Remarks to Generic Pharmaceutical Association, 20 September 2005

WASHINGTON, Sept. 20, 2005 - I know you are deeply interested in the patent reform legislation and generic biologicals and I intend to devote most of my remarks to those two issues.

However, there are other issues which I want to mention to you that will help explain why these two important matters are not front burner issues as the first session of the 109th Congress comes to an end this fall.

You all know that the Judiciary Committee and full Senate are working on the nomination of Judge John Roberts to be the next Chief Justice of the United States. And once we complete work on that, we will work on another Supreme Court vacancy that may take until December.

As well, there are many other important issues such as Hurricane Katrina relief efforts, implementation of the Medicare prescription drug program, and the budget reconciliation process.

So the Congress has a busy schedule for the next few months.

For example, take budget reconciliation. This is the first budget reconciliation package that Congress has considered since the Balanced Budget Act of 1997. While the deadline for Committees to report their packages to the Budget Committee has been extended to October 26, 2005, the individual Committees with reconciliation instructions have been considering their packages since the summer. As a senior member of the Finance Committee, I can tell you that we are taking our instructions from the budget resolution very seriously and have been meeting since the early summer. While the Finance Committee is currently focusing on the Katrina relief package, it will not be long before we go back to the budget reconciliation negotiations.

The Senate also must consider all of the outstanding appropriations bills – currently, we are considering the Agriculture Appropriations legislation where we expect several controversial amendments to be offered on the Senate floor. These amendments could include the Vitter-Coburn amendment on drug importation and possibly another proposal on making the Plan B contraception pill available over-the-counter.

So, as you can see, we have a busy fall ahead of us and there is not a lot of time to consider other issues. But that's where all of you are key – you must be persistent and raise your priorities with your representatives in both the House and the Senate.

As one of your good friends in the Senate, I am telling you this for your own good. You need to get on the Congress' radar screen. I will do everything I can to help you, but you have to do the leg work.

**Patent Reform**

As I am sure you all are aware, patent reform is one of the most significant intellectual property issues currently in Congress. In working on this issue, I have tried to come up with a few principles and goals that I hope will guide some of the debate in the Senate and any eventual legislation.

Goal 1: Increasing patent quality.

Many of the current complaints about the patent system that I have heard deal with the number of suspect and over-broad patents that are issued. Thus, in considering patent reform, it appears to me that Congress and the PTO must cooperate to find ways to increase patent quality. Increased resources for the PTO will have some beneficial effect on patent quality, but I am convinced that more money will solve only part of problem.

Human errors in the application and examination processes, efforts of applicants to obtain broad claims to maximize the scope of their exclusive rights, and occasional malfeasance by applicants result in a significant number of suspect or bad patents. Although the PTO does a reasonably good job, enough bad patents still issue to cause some real problems. For obvious reasons, this leads to inefficient litigation, as well as significant economic dislocation and business risk. Suspect patents also appear to enable abusive litigation. Because bad patents are generally of little value to productive companies, in many cases their value is maximized by using them as a basis for infringement suits against deep-pocket defendants.

I am convinced that part of the current problem with suspect patents – and the resulting increase in litigation – stems from the lack of an effective administrative mechanism for reconsidering or modifying suspect and over-broad patents. This forces legitimate disputes into court and increases the potential for abusive litigation in illegitimate disputes. The current administrative process of reexamination is fundamentally flawed and, as a result, goes virtually unused. Although there is little consensus regarding the details, there is some consensus for addressing this problem either by fixing the existing re-examination process or by creating a post-grant review process so that third parties can challenge suspect patents in an administrative process. Similarly, many support allowing third parties to submit prior art that is relevant to an applicant's patent claims before the patent is issued.

I believe that any patent reform legislation that is to have a long-term impact will necessarily include one or more of these proposals.

Goal 2: Increasing international harmonization.

Over the past several decades, various experts, including academics, presidential commissions, and blue-ribbon panels have advocated increased harmonization between the U.S. patent system and those of other countries. Advocates of harmonization often cite three different types of anticipated benefits from increased harmonization. First – faster, more predictable patentability determinations; Second – decreased litigation costs in the long term; and, Third – reduced redundancy in patent examination and associated decreases in costs to patent holders in obtaining global patent protection. However, there are those who question the need for increased harmonization or who oppose it outright. Some argue that harmonization would disadvantage

specific interests or groups, including independent inventors, small businesses, non-profit entities, and educational institutions. Others argue that the potential efficiencies of harmonization simply do not outweigh the perceived benefits of some of the unique aspects of U.S. patent law.

In the context of patent reform legislation, we are working through the arguments regarding moving from our traditional first-to-invent regime to the internationally adopted first-to-file system; eliminating the best-mode requirement; requiring publication of all patent applications after 18 months; and, moving toward a more uniform definition of prior art that is closer to what is used internationally.

It seems clear that some of the harmonization proposals have significant support both in Congress and in the patent community. I would anticipate that aspects of international harmonization will be included in patent reform legislation this Congress.

Goal 3 – Decreasing unwarranted or abusive patent litigation.

By all accounts, patent litigation has become a significant problem in some industries and for some types of litigants. There are a number of factors in patent law that drive up the cost and uncertainty of litigation in ways that appear to be unjustified. However, some of the principal problems and costs associated with patent litigation are not uniform across industrial sectors. This has led to substantial and sometimes vociferous disagreements about the nature of the underlying problems and, thus, what the appropriate solutions might be.

A variety of industries and companies argue that a certain class of patent holders – who some less-than-affectionately characterize as "patent trolls" – attempt to secure disproportionately high settlements from defendants that cannot afford to take an intolerably high-risk of treble damage awards or massive lost profits if an injunction keeps their product off the market during and after litigation.

Two approaches to dealing with the current problem of patent litigation have emerged in the patent reform debate.

One focuses on eliminating subjective elements and fact-intensive inquiries from patent litigation. The other, and much more controversial, approach involves altering the remedies available to patent holders in litigation.

Subjective and unduly fact-intensive elements inherently lead to higher litigation costs and increased certainty in virtually all areas of litigation. They increase costs at most stages of litigation, but the impact on pre-trial discovery costs is the most significant. Because they open the door to extensive discovery, they are also susceptible to abuse when used for strategic purposes, such as uncovering competitive information from competitors or threatening costly discovery to force settlements of unmeritorious suits. Nevertheless, the pertinent question is not simply whether the subjective elements of patent law increase cost and decrease certainty, but whether there is some purpose served by retaining such elements despite the costs. There are at least three such elements that appear to have little or no justification given the associated litigation costs.

Many possible approaches have been suggested in this area, but the most serious discussion revolves around eliminating or altering three subjective elements: the doctrine of willfulness, the best mode requirement, and the doctrine of inequitable conduct. We in Congress are committed to finding ways to simplify litigation, curb unproductive discovery, limit opportunities for abuse, and decrease litigation uncertainty, but we have not yet reached consensus on what approach best accomplishes this goal with respect to these subjective elements.

The second – and much more contentious – approach to addressing the patent litigation problem involves altering the remedies available to a patent holder. This approach is based on the assertion that current law imposes disproportionate liability and business risk on legitimate enterprises.

As I have mentioned, the costs of allegedly-abusive litigation tactics do not seem to be evenly spread across industries or parties, and any legislative effort in this area means wrestling with many devilish details to balance the interests of numerous different industries. Two challenges we face revolve around the advisability of altering the standard for obtaining injunctions; and codifying a rule for the apportionment of damages.

Altering the standard for determining whether injunctive relief should be granted in a patent infringement case has emerged as perhaps the most contentious issue in the patent reform debate. Large high-tech companies, many of which have products covered by thousands of patents, believe that some change in current law is necessary to prevent what they consider as something akin to legalized extortion by plaintiffs who use the threat of an injunction to obtain settlements that are allegedly disproportionate to the value of the patent that is infringed.

Because the profitable life of many high-tech products is relatively short, an injunction that keeps these products off the market for a year or two can threaten the profitability or even the viability of a small or mid-sized tech company, which arguably forces these companies to settle cases for much more than the claims are actually worth.

To add to the difficulty, some believe there appear to be quite a few over-broad patents in these areas, resulting in a situation where an infringement suit might be successful even though it would have failed if the patent claims were written properly. The tech industry has dealt with this problem in part through cross-licensing to avoid the mutually assured destruction that would accompany aggressive enforcement of all relevant patent rights.

Cross-licensing only works as a solution if the other potential litigants face a comparable threat from the available remedies. Many tech companies argue that the main threat is not from other legitimate companies, it is from overly-aggressive patent holders and their attorneys who use the disproportionate threat of an injunction to extort large settlements based on nearly worthless patents. It is alleged that these types of patent holders, commonly referred to as patent trolls or licensing shops have no interest in cross-licensing because – in the most extreme examples – they don't make or sell anything and therefore have no business risk from an injunction. They allegedly exist predominantly for the purpose of threatening litigation to obtain settlements.

Interestingly, among the most vocal critics of the high tech sector's desire to amend the injunctive relief provisions in current law are the pharmaceutical and biotech industries, independent

inventors, and some small business interests. Generally, the products patented by the drug companies and small inventors are discrete inventions covered by relatively few patents. They rely on the absolute exclusivity of their patent rights, often enforced by injunctions, to ensure that they are able to commercialize their inventions and enjoy the fruits of their innovation. Similarly, small inventors rely on injunctive relief to equalize the playing field when competing against larger, better-funded enterprises.

This same type of debate is playing out with respect to the provisions authorizing damages in patent litigation.

I understand that this issue is most important to the software industry. It claims that under current law a patent holder who successfully sues a software company for infringement may be rewarded well beyond the actual value that the invention contributes to a product.

The argument is that, under some damages theories, a plaintiff can receive damages based on the value of the market for an entire product when the patented invention is only a small part of the actual product.

For example, suppose damages were based on the market value for an entire car when the patent only covered the windshield wiper motor or some other component out of hundreds. Crafting language that satisfactorily codifies a proportional contribution measure of damages is just one of the many challenges that Congress faces in the process of drafting patent reform legislation.

As you may have guessed from my remarks, my sense is that patent reform still has a fair distance to go before a sufficient consensus forms in Congress around a particular set of reforms. In my experience, this is not uncommon for patent reform legislation, which often takes several years from conception to enactment.

Turning to another topic that is near and dear to most everyone here, including me, I would like to spend a few minutes on the issue of follow-on biologics.

**Follow-on Biologics**

As most of you know, I have for some time been deeply interested in the issue of devising an appropriate path for the approval of off-patent follow-on biologic medicine.

I am firmly convinced that the day will come when this vision becomes reality. Much groundwork needs to be done before a fast track approval process for follow-on biologics is adopted by the Food and Drug Administration.

In my former role as Chairman of the Senate Judiciary Committee, I held a hearing on generic biologics in the summer of 2004. It is a complex subject area that involves law, economics, science and medicine.

While there can be no doubt that the law and science surrounding this issue are extremely complicated, I also have confidence that scientists and policymakers will be up to the challenge.

Biologic medicines are large complex proteins made from living cells, often by recombinant DNA technology. The area of biologics is of growing medical and economic importance. The good news for the American public is that this field is currently in its infancy, so we can expect many important therapeutic breakthroughs to emerge over the next few decades.

Now that we have mapped the structure of the human genome, we are in position to understand and catalog the function of the 30,000 human genes and the thousands of proteins they encode and regulate. Nothing less than a revolution in our understanding of human health and disease is well underway.

I am so proud of the fact that scientists at the Huntsman Cancer Institute at the University of Utah are some of the ones leading the way.

For example, it is the hope of many, including me, that biological products such as those that may one day be developed from embryonic stem cells could lead to cures to many diseases that cannot be successfully treated today. We hope that biologicals derived from stem cell research will one day help conquer diseases like diabetes, Alzheimer's, MS, Parkinson's, ALS, heart disease and many types of cancer. Biopharmaceuticals appear to represent the future of medicine.

On the business side, the biotechnology market today represents over $30 billion in annual sales. Experts project this sector will double to over $60 billion by the year 2010. Consistent with these projections, we have seen a large influx in the numbers of biologic product applications submitted to FDA.

There are now over 1,000 FDA-approved biologic products on the market, with an additional 350 in various stages of human clinical testing, and over 1,000 others in the development pipeline.

Let's face the facts: The old model of large-patient-population, small-molecule medicine is gradually shifting more and more toward large-molecule, small-patient-population therapies. The day may even come when individualized therapies will become common. These developments, of course, are not around the corner, nor will they occur without a substantial investment of time, creative energy, and money.

We can all be sure of one thing: When medical breakthroughs occur, patients and their families and loved ones will want access to these new products as soon as they can get them.

And we can be certain of another thing – and this is where all of you in this room come into play – the patients and their families and third-party payers will want to pay as little as possible for them.

Some caution that these new therapeutic protein molecules require more effort to discover, manufacture and administer than conventional small-molecule, chemically-synthesized drugs. As a result, many of these new biological products are more expensive than old-fashioned drug products. Some of these new wonder therapies can cost over $10,000 per course of treatment. For example, human growth hormone can cost $25,000 per year.

As I have said for more than five years now, cost factors alone compel a full examination and public discussion of the merits of developing and implementing a fast-track review and approval system that can reduce the price of biopharmaceuticals once patents expire. Solely from a regulatory reform perspective, I believe it should always be the goal of government to employ the least burdensome regulatory approach without compromising other important considerations, such as in this case, patient safety and protection of intellectual property.

Former Commissioner of Food and Drugs – and current CMS Administrator – Dr. Mark McClellan, clearly recognized the confluence of medical, economic and regulatory forces at play. I think that Dr. McClellan training in both medicine and economics made him especially receptive of the reality of the need for patients to get the best and most affordable treatments. In his new capacity as Administrator for the Centers for Medicare and Medicaid Services, I am sure that Dr. McClellan remains supportive of finding ways to cut the cost of medicine paid for by the federal government.

Similarly, I am hopeful that under the leadership of our new Commissioner, Dr. Lester Crawford, the FDA will take a proactive leadership position in this important area. I have urged him to devote adequate resources for to this effort and to make it one of the agency's top priorities in the area of drug regulation.

In fact, in order to help the agency to focus on this matter I inserted language in the report to accompany FDA's funding bill, the Agriculture Appropriations bill. My language requires the FDA to report on its efforts with respect to developing a regulatory pathway for off-patent, follow-on biologics.

Prior to his confirmation, I spoke to Dr. Crawford on several occasions about the follow-on biologics issue, and he has assured me that the FDA will be issuing a guidance document on this by the end of the year. I expect Commissioner Crawford and the FDA to meet this commitment.

The bad news is that apparently my language may have ruffled some feathers in some quarters as I understand that one of my colleagues in the Senate is trying to include bill language to preclude the FDA from exploring whether section 505(b)(2) of the Food, Drug, and Cosmetic Act may be used by the agency as a mechanism to review and approve follow-on biologics.

Rather than short circuit the system at this point, like many others, I would benefit from receiving the FDA's formal response to the several citizen petition's seeking FDA view's of whether, and to what extent, section 505(b)(2) might be properly available in this regard. Unfortunately, one thing that has not changed under Dr. Crawford's leadership to date is that the FDA continues its long record of taking its good old time in responding to controversial citizens' petitions.

Nevertheless, with ever-rising health care costs we can ill afford to avoid a debate over the proper regulation of follow-on biologics. The simple truth is that we simply cannot sustain over time programs such as Medicare unless we seriously consider what steps might prudently be taken to change an FDA regulatory system that essentially acts as a secondary patent to keep off-patent biological products off the market.

I emphasize that long term patient safety and product efficacy must never be compromised for the safe of short run cost savings. The task before policymakers is to attempt to maintain or increase product safety and efficacy at the same time we consider ways to eliminate unnecessary regulatory burdens for off-patent biological products.

I will stipulate that this is a tall order. But so was the creation of the ANDA system. And after 20 years, I think we can all say that the generic drug industry has fulfilled and even exceeded our hopes when Hatch-Waxman was passed in 1984.

Your industry now represents about one-half of all prescriptions sold in the United States. Patients have good reason to be confident in your products. And both patients and payers are pleased with the fact that more is left in their pocketbooks when generic drug products are prescribed.

It may prove difficult to make some generic equivalents of off-patent biologicals. Some products will be hard, and perhaps impossible, to manufacture. It is my understanding that this will be the exception, not the rule.

It may be appropriate that many, if not all, follow-on biologicals will require at least some form of truncated human clinical testing. If that is the case, so be it.

I also think, given the cost savings that we may be able to achieve, that the federal government should consider developing process validation guidelines that can be used to help establish the critical manufacturing steps and assay parameters for certain medically or commercially significant off-patent biological products.

Further, we should consider using organizations such as the United States Pharmacopeia or the Institute of Medicine, in collaboration with the FDA and other interested parties, to help identify and address the technical issues that need to be resolved in order to fast-track approvals for off-patent biopharmaceuticals.

It may be that this initiative will end up requiring legislation. As a co-author of the Hatch-Waxman Act of 1984, I think that whatever we do on the legislative front should retain the principle of balancing the incentives for both pioneer and generic drug firms.

While I support developing an abbreviated approval system for off-patent biologics, we must continue to respect the intellectual property of the research-based firms because this is the foundation of the entire pharmaceutical industry.

Accordingly, it is important to consider whether our current intellectual property laws relating to pharmaceutical research and development are adequate to promote large-molecule, small-patient-population medicine in the future. Some of these issues are being addressed in the on-going debate over reforming the general patent code. Over the last several months – and no doubt in the next several months – issues, such as first-inventor-to-file and injunctive relief, have often been debated through the perspective of the various stakeholders in the pharmaceutical industry.

Moreover, aside from the general reform of the Patent Code in Title 35, I have long been concerned about the way we treat process patents under the provisions of the Hatch-Waxman Act. I think the exclusion of process patents for restoration under the law should be re-examined in this new era of potentially patient-specific medicine in which process patents may become relatively more important.

Let me close by stating that developing a new system for the review and approval of off-patent, follow-on biologics will not be easy. Some are, and will continue to be, inclined to resist. I am fully aware, and am often reminded, that some in the biotechnology industry think the adoption of a fast-track approval process for off-patent biologics is their worst nightmare.

Twenty years ago, we faced many similar challenges, and many, many nay-sayers, in fairly balancing the incentives and various interests when we came together on Waxman-Hatch.

While some will attempt to just say no, I will continue to urge all affected and interested parties to engage in a constructive public policy dialogue that identifies the key scientific and legal obstacles that must be overcome in order to create a fast-track approval system for off-patent biologics.

At the same time, we should be open to discussing ideas that will improve the legal environment for pioneer biotechnology firms.

That is what we did back in 1984 and that is what we need to do today – work together to balance the incentives in the law so that the American public will continue to reap the benefits of both innovate and affordable medicines.

With your help, and the work of many others, I think the day will come when a system of review and approval for follow-on biologicals will be put into place at the FDA.

In order to make this day come sooner, I hope that you will spend part of your time in Washington meeting with your Representatives and Senators to help explain to them what is at stake in creating this important new regulatory pathway.

I wish you good luck in your educational efforts on the Hill, in this conference, and with your business plans.

If you do take my advice and visit your Senators, you might want to mention that Senator Hatch urges everyone to vote for Judge Roberts – but that is another matter.

Thank you.

Contact: Peter Carr, (202) 224-9854