

Current Federal law and regulations attempt to carefully balance the goals of innovation and accessibility. New drugs, on average, are sold for 11 years under patent protection, then generic versions become available. Unfortunately, the careful balance of the law is being undermined.

The FTC investigation discovered that some brand-name drug manufacturers may have manipulated the law to delay the approval of competing generic drugs. When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness. In this way, the brand-name company buys time through repeated delays called automatic stays that freeze the status quo as the legal complexities are sorted out.

In the meantime, the lower cost generic drug is shut out of the market. These delays have gone on, in some cases, for 37 months or 53 months or 65 months. This is not how Congress intended the law to work. Today I'm taking action to close the loopholes, to promote fair competition, and to reduce the cost of prescription drugs in America.

The Food and Drug Administration is issuing a proposed rule that will permit only one automatic stay per generic drug application, a move that in many cases will reduce the public's wait for generic drugs by years. Some patents will no longer be entitled to protections like the 30-month stay, including patents on packaging and others that have little or nothing to do with valuable innovation and drug therapy.

These steps we take today will not undermine patent protection. Instead, we are enforcing the original intent of a good law. Our message to brand-name manufacturers is clear: You deserve the fair rewards of your research and development; you do not have the right to keep generic drugs off the market for frivolous reasons.

Over the next 3 years, about 200 drug patents are set to expire. By cutting out delays and maneuvering, our reforms will yield cost savings of more than \$3 billion a year. Those savings will come to employer health plans, to State Medicaid programs, and to seniors when they buy medicines on their own.

This is another important advance in the cause of bringing affordable prescription drugs to our seniors. Already, we have cleared the way for States to provide prescription drug coverage to more seniors with modest means through our Medicaid Pharmacy Plus Program. We're working to provide seniors on Medicare with drug cards that provide discounts from drug manufacturers on brand-name drugs, like the ones available in private health plans. And we will not rest until we've reformed and strengthened the Medicare program, itself, so that a prescription drug benefit is available to every senior in America.

The House of Representatives took strong action in passing legislation to improve Medicare. The Senate failed to act. The challenge of health care reform is to increase access to quality care, while we preserve the finest health care system in the world.

I thank the good people at the FTC and the FDA for helping in this effort and for working to make these critical drugs more affordable for every American.

Thank you for coming.

NOTE: The President spoke at 8:33 a.m. in the Rose Garden at the White House. The Office of the Press Secretary also released a Spanish language transcript of these remarks.

Remarks Following Discussions With Secretary General Lord Robertson of the North Atlantic Treaty Organization and an Exchange With Reporters

October 21, 2002

President Bush. It's my honor to welcome Lord Robertson back to the Oval Office. I think we've met, gosh, five—four or five times since I've been the President. I've enjoyed every meeting. He does a great job at NATO. NATO is an incredibly important part of U.S. foreign policy. I appreciate the alliance.

We are mainly discussing issues that we will confront and/or deal with in Prague, including NATO expansion. He's soliciting the views of the administration. I told him that we would give him a definite answer about our views on expansion in a couple of weeks,

and that timetable seemed satisfactory with him.

But Lord Robertson, welcome back. I appreciate you being here. Thanks for your strong leadership.

Lord Robertson. I'm delighted to be again in the Oval Office, Mr. President.

And the President has shown, not just by meetings with me but in every other way possible, his and his administration's commitment to NATO and to the strength of this trans-Atlantic alliance that has bound together these democratic and freedom-loving states over all of the years.

We're now a month to the day away from the Prague summit, probably the most important summit meeting in NATO's history, a transformation summit where NATO has to transform itself to deal with the threats and the challenges of the 21st century. And I believe we will have a good package on new members, a robust enlargement, new capabilities to deal with terrorism and to deal with the other challenges and nightmares that we may face ahead in the future, and new relationships with Russia, with Ukraine, with our partner countries, building the world's largest permanent alliance and one which the world can rely on.

President Bush. Three questions. Fournier [Ron Fournier, Associated Press].

North Korea

Q. Sir, is North Korea an imminent threat to the United States, and what consequences, if any, will it face for hiding its nuclear program from you?

President Bush. One, we had a bit of troubling news when we discovered the fact that, contrary to what we had been led to believe, that they were enriching uranium with the idea of developing a nuclear weapon. I say "troubling news," obviously, because we felt like they had given their word they weren't going to do this.

I view this as an opportunity to work with our friends in the region and work with other countries in the region to ally against proliferation of serious weapons and to convince Kim Chong-il that he must disarm. To this end, I'm going to be talking to Jiang Zemin at Crawford. I look forward to a good discussion with the President of China about how

we can work together to take our relationship to a new level in dealing with the true threats of the 21st century.

I will see the leaders of Japan and South Korea and Russia the next day, in Mexico. I intend to make this an important topic of our discussions. This is a chance for people who love freedom and peace to work together to deal with a—to deal with an emerging threat. I believe we can deal with this threat peacefully, particularly if we work together. So this is an opportunity to work together.

Q. They're not an imminent threat, though?

President Bush. You know, that's an operative word. We view this very seriously. It is a troubling discovery, and it's a discovery that we intend to work with our friends to deal with. I believe we can do it peacefully. I look forward to working with people to encourage them that we must convince Kim Chong-il to disarm for the sake of peace. And the people who have got the most at stake, of course, in this posture are the people who are his neighbors.

Arshad [Arshad Mohammed, Reuters].

Nature of Iraqi Threat

Q. Mr. President, can you explain so the boys in Lubbock can understand—

President Bush. Crawford or Lubbock?

Q. Lubbock or Crawford, both—

President Bush. Lubbock is a little more sophisticated than Crawford, Arshad. [Laughter]

Q. Crawford, then.

President Bush. Or Scotland, for that matter.

Q. Why—

President Bush. Yes, Arshad.

Q. Why you threaten military action against Iraq, but you believe that Korea's nuclear weapons program only merits diplomatic efforts?

President Bush. Saddam Hussein is unique, in this sense: He has thumbed his nose at the world for 11 years. The United Nations has passed 16 resolutions to deal with this man, and the resolutions are all aimed at disarmament, amongst other things. And for 11 years, he said, "No, I refuse to disarm."

Now, what makes him even more unique is the fact he's actually gassed his own people. He has used weapons of mass destruction on neighboring countries, and he's used weapons of mass destruction on his own citizenry. He wants to have a nuclear weapon. He has made it very clear, he hates the United States, and as importantly, he hates friends of ours.

We've tried diplomacy. We're trying it one more time. I believe the free world, if we make up our mind to, can disarm this man peacefully.

But, if not, there's—we have the will and the desire, as do other nations, to disarm Saddam. It's up to him to make that decision, and it's up to the United Nations. And we'll determine here soon whether the United Nations has got the will, and then it's up to Saddam to make the decision.

Stretch [Richard Keil, Bloomberg News].

Regime Change in Iraq

Q. Mr. President, again, for the good people of Crawford—

President Bush. Yes. It's been a big day for Crawford.

Q. If you can explain this in a way that they and the rest of us will understand, there is some hints over the weekend, the possibility that taking weapons of mass destruction out of Iraq is our goal, raising the possibility or the implication that he could somehow remain in power.

Can you say authoritatively and declaratively whether we can achieve—you can achieve—if you can achieve your aims there in a way that leaves him still in office?

President Bush. The stated policy of the United States is regime change because for 11 years, Saddam Hussein has ignored the United Nations and the free world. For 11 years, he has—he said, “Look, you passed all these resolutions. I could care less what you passed.” And that's why the stated policy of our Government, the previous administration and this administration, is regime change—because we don't believe he is going to change.

However, if he were to meet all the conditions of the United Nations, the conditions that I've described very clearly in terms that

everybody can understand, that in itself will signal the regime has changed.

NOTE: The President spoke at 3:35 p.m. in the Oval Office at the White House. In his remarks, he referred to General Secretary Kim Chong-il of North Korea; President Jiang Zemin of China; Prime Minister Junichiro Koizumi of Japan; President Kim Dae-jung of South Korea; President Vladimir Putin of Russia; and President Saddam Hussein of Iraq.

Statement on Signing the Sudan Peace Act

October 21, 2002

I have today signed into law H.R. 5531, the “Sudan Peace Act.” This Act demonstrates the clear resolve of the United States to promote a lasting, just peace; human rights; and freedom from persecution for the people of Sudan. The Act is designed to help address the evils inflicted on the people of Sudan by their government—including senseless suffering, use of emergency food relief as a weapon of war, and the practice of slavery—and to press the parties, and in particular the Sudanese Government, to complete in good faith the negotiations to end the war.

Section 6(b) of the Act purports to direct or burden the conduct of negotiations by the executive branch with foreign governments, international financial institutions, and the United Nations Security Council and purports to establish U.S. foreign policy objectives. The executive branch shall construe these provisions as advisory because such provisions, if construed as mandatory, would impermissibly interfere with the President's exercise of his constitutional authorities to conduct the Nation's foreign affairs, participate in international negotiations, and supervise the unitary executive branch.

Several provisions of the Act purport to require executive branch reports to congressional committees concerning the contents of U.S. diplomatic advocacy, plans for U.S. diplomatic activities to achieve particular foreign policy objectives, and information on particular activities abroad. The executive branch shall construe these provisions in a