Testimony of

Mr. Sheldon Bradshaw

August 1, 2003

Testimony of Sheldon Bradshaw
Deputy Assistant Attorney General
Office of Legal Counsel
U.S. Department of Justice
on
H.R. 1, Medicare Prescription Drug and Modernization Act of 2003

Thank you, Mr. Chairman, for inviting me here today to provide the Administration's views on H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003. My testimony today will focus on a provision in the Senate version of the bill, section 702(c), which declares that the federal courts shall have subject matter jurisdiction over certain declaratory judgment actions. Specifically, the provision in question provides that the failure of a patent owner to bring an action for patent infringement against a pharmaceutical company that files a new drug application with the FDA that is based on one of its patents within 45 days of receipt of notice of the application "shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States" to hear an action brought by the applicant under the Declaratory Judgment Act, 28 U.S.C. § 2201.

On June 17, 2003, I provided this Committee with the Administration's tentative views on a similar provision contained in S. 1225, the Greater Access to Affordable Pharmaceuticals Act. At that time, the Administration had not yet formed a definitive view on whether cases brought pursuant to such a provision would satisfy the Article III case or controversy requirement. I did, however, make several general observations about the matter. I noted that, among other things, the case or controversy requirement set forth in the Declaratory Judgment Act was constitutionally compelled and that, like other Article III requirements, it could not be waived by Congress. Having now had an opportunity to examine the provision in greater detail, the Administration is of the view that, in its present form, section 702(c) is inconsistent with Article III of the Constitution. This provision, which does not appear in the House version of the bill, attempts to vest the lower federal courts with jurisdiction over disputes that, because of Article III's case or controversy requirement, the Constitution does not empower these courts to hear. Accordingly, it is the view of the Administration that this provision should either be deleted from the bill or rewritten.

Both the Senate and House versions of H.R. 1 make amendments to the process by which new drug applications are approved. The bills require that certain applicants give notice to existing owners of a patent or to holders of an approved application. The notice must provide a detailed factual and legal basis for why the application does not infringe the recipient's patent or why the recipient's patent is invalid. If the recipient of the notice sues for infringement within 45 days following receipt, it receives a significant benefit. Among other benefits, the application may not

be approved until the earliest of the resolution of the infringement suit, the expiration of the relevant patents or the passage of thirty months from the date of the notice.

Both the Senate and the House versions of the bill provide that if the patent holder does not bring suit within the 45-day period, the applicant may then bring a declaratory judgment action for non-infringement or patent invalidity. The Senate, but not the House, version of the bill, goes further and provides that "the failure of the owner of the patent to bring an action for infringement of a patent [within the 45-day period] shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States" to hear an action brought under the Declaratory Judgment Act, 28 U.S.C. § 2201. Herein lies the constitutional infirmity.

The Declaratory Judgment Act requires that a dispute be an "actual controversy" before the federal courts have subject matter jurisdiction over actions to declare the rights of the parties. The Senate version of H.R. 1 purports to declare this requirement satisfied in every case by the failure of the patent holder to bring an action within 45 days, and thus to vest the federal courts with subject matter jurisdiction in all of these cases. Congress, however, cannot so declare. The limitations on the federal courts' jurisdiction emanate from the Constitution, not merely from the "actual controversy" requirement of the Declaratory Judgment Act.

Under the Constitution, federal courts have jurisdiction over a dispute only if it is a "case or controversy" within the meaning of Article III. This restriction on the courts' authority is fundamental to the separation of powers established by the Constitution and enjoins the courts from issuing advisory opinions. This requirement consequently operates as a limitation on Congress's power to grant the courts jurisdiction. Put simply, Congress cannot expand the courts' power to hear cases beyond what the Constitution itself provides.

Courts have read the Declaratory Judgment Act's "actual controversy" language to track the Constitution's "case or controversy" requirement. The Supreme Court has "adjudged [the Act] constitutional only by interpreting it to confine the declaratory judgment remedy within conventional 'case or controversy' limits." If the Declaratory Judgment Act were effectively amended with respect to these patent cases, satisfaction of the statutory "actual controversy" requirement would no longer be sufficient to grant the courts jurisdiction. The courts would still have to satisfy themselves that the dispute was a "case or controversy" under the Constitution. Congress cannot amend this constitutional standard. Although Congress may declare that a certain set of facts fulfills a statutory requirement, it cannot declare Article III's limitations satisfied. If it did so, it would be improperly intruding on the court's province to interpret the Constitution. Just as Congress may not declare Article III's standing requirement satisfied, so may it not declare Article III's "case or controversy" limitation satisfied. Congress simply cannot expand the federal court's jurisdiction beyond the bounds established by the Constitution.

Section 701(c) of the Senate version of H.R. 1 thus can have no effect. In many cases, the actions brought following the 45-day period will meet the Constitutional "case or controversy" requirement independently of section 701(c)'s declaration. As applied to these cases, the provision is constitutional, but without purpose. Currently, to determine whether Article III and the Declaratory Judgment Act are satisfied in patent disputes, federal courts have asked whether the applicant has a "reasonable apprehension" that the patent owner will sue for infringement.

Applying this standard, courts look to a variety of factors, including communications between the patent holder and the applicant and the actions of the patent holder with respect to other possible infringers. Indeed, in light of the statutory benefit conferred on the patent owner if it sues within the 45-day period, it is likely that a court would consider the applicant's reasonable apprehension to be diminished if the patent holder does not sue for infringement within that time. Over disputes that the courts determine are insufficiently definite and concrete to rise to a "case or controversy," the Constitution prohibits Congress from granting the courts jurisdiction. Accordingly, the courts would decline to hear such cases and section 701(c) would again be rendered ineffectual.

For these reasons, it is the view of the Administration that the Senate version of H.R. 1 should be amended to delete the language purporting to confer the federal courts with subject matter jurisdiction whenever a recipient of the required notice has not sued within the 45-day waiting period.