



GEORGETOWN UNIVERSITY LAW CENTER

May 29, 2007

The Honorable Patrick J. Leahy
United States Senate
Committee on the Judiciary
Washington, DC 20510-6275

Dear Senator Leahy:

Thank you for the opportunity to reply to the additional questions posed by your colleagues on the United States Senate Committee on the Judiciary. I submit these responses on my own behalf. These views are not necessarily those of any other individual, enterprise, or organization.

Questions from Senator Specter

1. If we change the law to make the 271(g) defenses apply in the ITC, wouldn't that create an incentive for manufacturers abroad to infringe US process patents in other countries for subsequent importation to the U.S.?

Absent empirical evidence on this issue, I simply do not stand in a position to be able to respond to this question in a responsible way. I observe, however, that this amendment could just as readily be seen as encouraging manufacturing in the United States. Both U.S. and foreign firms manufacture complex products in the United States, and they not infrequently import various components of those products from abroad. If U.S. process patents regulate the importation of those components—even where the relationship between the patent and the component is tangential—then the failure to apply the § 271(g) defenses in ITC actions may discourage firms from domestic manufacture altogether.

I also hasten to note that the issue addressed in the hearing of May 1, 2007, was not the proposed elimination of the rule that importation of the product of a process patented in the United States will ordinarily infringe the U.S. patent. Rather, the issue was the extent of a U.S. process patent's extraterritorial interest, and in particular whether products that bear only a tangential relationship to a patented process should still fall within the exclusionary scope of that patent. The incentive that this question suggests is, at most, the incentive to practice a patented process overseas, but then either (1) materially change the product of that process, or (2) ensure that the product of that process becomes a trivial and nonessential component of another product, prior to importing that product into the United States. When it enacted § 271(g), Congress made the judgment that a cause of action for patent infringement in the United States was not justified in these remote circumstances.

The current disconnect between the Patent and Tariff Acts causes the federal administrative and judicial apparatus to continue to react to these scenarios, in contradiction to congressional intent in enacting the Process Patents Amendment Act.

2. Mr. Thomas, is there an actual problem that is in need of Congressional attention or only the potential for a problem? The Federal Circuit has yet to apply the dicta of Kinik and with so many other issues being presented to Congress in the patent reform debate, is there a reason why Congress should amend this portion of the patent code when it is clear that there is still a substantial question as to whether it is necessary?

Indications exist that the disharmony in process patent enforcement may constitute a current problem, rather than merely a potential one. Scholarly commentary has opined that the disjunction between the Patent Act and the Tariff Act violates commitments made by the United States when joining the World Trade Organization. Providing domestic industry with more favorable substantive patent law rules also conflicts with longstanding U.S. policy to improve intellectual property protection available to domestic innovators in foreign markets. The number of products—including medications and other health-related products—that have been denied to U.S. consumers, based upon their tangential relationship to a U.S. process patent, is also unknowable.

It should be also be appreciated that Congress has historically intervened in patent matters on an irregular basis. The last major overhaul of the patent code took place in 1952. Current discussion concerning omnibus patent reform may provide members of Congress, and their staff, with a level of sophistication concerning the patent system that may not be easily reconstructed in the future. As a result, current patent reform initiatives may provide a moment of opportunity for consideration of this fairly technical issue within the patent and trade laws.

Questions from Senator Whitehouse

1. Do you think it is appropriate for Congress to step into the middle of a dispute between two parties and change the rules while the litigation is ongoing? While it may not be unprecedented, I think it would be an unwise course. Shouldn't Congress have a "don't intentionally and specifically interfere in litigation" policy?

I am aware that there is an ongoing dispute between Amgen and Roche that implicates the applicability of § 271(g) issues before the ITC; that statement is essentially the extent of my knowledge as to that disagreement. It should be appreciated, however, that the current disharmony in U.S. process patent enforcement may transcend a particular litigation between two commercial rivals. Academic commentary suggests that this disjunction constitutes a continuing violation of commitments made by the United States when joining the World Trade Organization. We also have no reliable way of knowing the number of products that firms opt not to introduce into the U.S. marketplace due to concerns over process patent infringement—despite the tangential relationship between the U.S. patent

and the product that would ultimately be introduced into the United States. The expansion of the proprietary extraterritorial rights associated with U.S. process patents, in contradiction to congressional intent in framing the Process Patents Amendment Act, may result in higher prices and diminished supplies for U.S. consumers in such crucial areas as pharmaceuticals and other medical products. For these reasons, Congress may properly judge this issue to be one that encompasses policy concerns that extend beyond a particular lawsuit.

2. The ITC and the federal court systems have different purposes and grant different remedies. The ITC exists, in part, to protect American industry and trade—and it provides injunctive relief in the form of exclusion orders; the federal court system, among other things, protects individual rights—and provides relief in the form of damages. Doesn't it make sense that defendants in these different venues can avail themselves of different defenses?

It is true that the ITC and the federal courts have different purposes. Of course it is also true that the remedies vary between the two fora, in that the relief available from the ITC is essentially a subset of that available from the federal courts. These premises do not logically result in the conclusion that substantive patent law rules should vary between the ITC and the federal courts, however. The legal and economic instrument that the moving party invokes in both fora is the same: An issued U.S. patent. Whether the ultimate purpose of enforcing that patent is styled as protecting U.S. industry, or as vindicating the right of an individual participant within U.S. industry, compelling policy reasons indicate that substantive legal rights should not vary among different fora. Holding otherwise violates a fundamental axiom of a just system of laws, the intuitive norm that like cases should be resolved alike. It also leads to other deleterious consequences, including bypassing the balance that Congress achieved in enacting the Process Patents Amendments Act, as well as undermining the preclusive effect that ITC rulings ordinarily enjoy before the federal courts.

3. What would be the impact on the American economy, and on American jobs, if we were to expand on the number of affirmative defenses available to parties accused of infringing process patents before the ITC? Would it send piracy overseas by expanding the permissible uses of US process patents abroad?

Once again, absent empirical evidence on this issue, I simply do not stand in a position to be able to respond to this question in a responsible way. In a world where multinational enterprises increasingly operate distributed manufacturing facilities, however, the account that ecumenical application of the § 271(g) defenses would encourage offshoring or overseas patent infringement strikes me as at best incomplete. For example, both U.S. and foreign firms manufacture complex products in the United States, and they not infrequently import various components of those products from abroad. If U.S. process patents regulate the importation of those components—even where the relationship between the patent and the component is tangential—then the failure to apply the § 271(g) defenses in ITC actions may discourage firms from manufacturing in the United States in the first place.

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Thank you again for the opportunity to respond to these questions. If I may be of any further assistance, please do not hesitate to contact me at 202 662-9925, or at jrt6@law.georgetown.edu.

Sincerely yours,

John R. Thomas
Professor of Law