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The Honorable Patrick J. Leahy
Chairman, Committee on the Judiciary
U.S. Senate
Washington, DC 20510-6275

Dear Chairman Leahy,

This is in response to your questions following the Senate Judiciary Committee Hearing "Protecting Consumers by Protecting Intellectual Property". Please feel free to contact me with any more questions on this issue.

Question 1: To what extent do you think the protection of intellectual property is hampered by the scope of federal agencies' prosecutorial powers, as opposed to limited personnel and resources focused on enforcement?

Prosecutorial powers for Intellectual Property (IP) enforcement primarily rest with the Department of Justice. Although the Department of Justice sets the guidelines for all U.S. Attorney's offices, there are 93 U.S. Attorneys who establish their own guidelines that direct the level of support for IP matters by Federal agencies. IP matters do not generally appear to be as significant a priority as violent crimes, terrorism, or drug investigations except when a death occurs or there is a real safety risk to the public. Prosecutorial efforts are often hampered by the differing priorities of investigative agencies that frequently result in reduced investigative resources to support prosecution of IP matters. A vigorous enforcement effort cannot succeed without dedicated resources from investigative agencies that compliment prosecutorial resources. Strengthened enforcement is not about enhancement of resources, but about utilization of dedicated resources to properly address IP matters.

It has been our experience that counterfeit pharmaceutical and medical device products are generally manufactured overseas by unscrupulous businessmen who operate freely around the world and occasionally import these counterfeit products into the United States disguised as authentic products. Often they operate from jurisdictions that are lax in enforcement and prosecutorial efforts, which make the risk of being caught an acceptable cost of doing business. Vigorous enforcement and prosecutorial efforts need strong

criminal statutes and the ability to extradite major offenders as key components of a strong IP plan that is designed to protect the public.

In many cases the protection of IP and subsequent prosecutions are hampered by an inability of investigative agencies to obtain information on the spot during an investigation. Requiring the timely production of documentation, like an e-pedigree, or greater use of administrative subpoenas at the time of a search or inquiry would immediately allow federal agencies to develop a strong investigative plan that would greatly protect the public and result in more prosecutions. In this day of rapid communications, inexpensive technology and global movement of products the ability of investigative agencies to quickly follow an investigative trail is critical to the protection of the public.

Greater transparency for imported and exported shipments involving the contents of a container would allow investigators both private and public to obtain significant information about the destination of products that have been diverted or identified as being counterfeit. Greater transparency over imports and exports would significantly expand the utilization of private investigative resources to combat IPR issues.

Requiring internet sellers of pharmaceutical products and medical device products to be certified by an independent government agency with regulatory and enforcement powers would provide the public with a greater sense of confidence that on line pharmacies and auction sites are selling only legitimate products to U.S. patients. The ability to regularly audit both the issuance of prescriptions and the sale of online pharmaceutical products and medical devices by a federal agency would provide greater protection to the consumer. Auditing of purchasing records combined with a review of authentic e-pedigrees would enhance the ability to successfully prosecute sellers of unauthorized or counterfeit drugs and medical devices via the Internet. Consumers who use the internet for medical purchases have no ability to determine the authenticity of a product or the origin of the product, which puts the consumer at risk without some regulatory oversight.

Question 2: Who are the offenders for whom federal involvement is most needed? Are they primarily criminals engaged in large-scale operations, particularly ones that are international in scope or are involved with organized crime syndicates?

Federal involvement is needed when organized domestic and international criminal organizations are involved in IP matters. However counterfeiting operations are not always confined to organized crime syndicates or criminals involved in large-scale operations. Johnson & Johnson's experiences with counterfeiting operations have often indicated that there is a loose network of individuals or very small businesses that engage in both legitimate and

illegitimate transactions. These counterfeiters engage in counterfeiting because significant financial rewards are possible with a low risk of apprehension and conviction. Today's counterfeiters utilize global contacts, proprietary information, inexpensive and readily available technology and lax government involvement to pursue significant profits with little expenditures. Federal involvement is needed in IP investigations at the time of an initial report since it is difficult to identify the major offenders at the start of an investigation. A recent report from the Pharmaceutical Security Institute (PSI) indicated that stolen, counterfeit or diverted products have been found in 118 countries, which we believe indicates that involvement in counterfeiting is not solely limited to criminal syndicates.

Task forces that incorporate the skills and legal jurisdictions of local, state, federal and international law enforcement are critical to keep consumers safe from counterfeit products. The Federal Government should be a leader in coordinating the sharing of information among law enforcement and the private sector to significantly increase enforcement efforts in IP matters and assist in the development of credible and actionable intelligence. It is noteworthy that the National Intellectual Property Rights Coordination Center in Arlington, Virginia opened last week and is dedicated to the targeting of IPR crimes. The use of this center should enhance the efforts of law enforcement and private industry in better protecting the American consumer.

Prosecutorial and regulatory efforts from the Federal Government are key to protecting the supply chain and the ability to rapidly respond to reported incidents of counterfeiting or theft. An increase in criminal penalties for IP matters and an ability to swiftly extradite offenders for U.S. prosecution would demonstrate the commitment of the U.S. Government to protect IP rights both here at home and abroad.

Federal involvement is critically needed in instances where both the health and safety of consumers and multiple locations are involved. The ability to respond rapidly to multiple sites based on an initial report of an illness or injury is critical to insuring the safety of the public.

Thanks again for the opportunity to serve the committee.

Sincerely,

A handwritten signature in black ink that reads "Michael G. Rose". The signature is written in a cursive, flowing style.

Mike Rose
Vice President