

# GENERIC LINE<sup>®</sup>

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## Barr Urges FDA Globalization Bill Not Delay Generic Approvals

Barr's CEO urged lawmakers at a recent congressional hearing on a draft bill to enhance the FDA's authority to use risk-based criteria to schedule increased inspections of domestic or overseas drug-making facilities.

The draft bill is aimed at preventing imports of unsafe products like the tainted heparin linked to 81 deaths in the U.S. due to contamination of its active pharmaceutical ingredient at a Chinese plant, Changzhou SPL.

Barr CEO Christine Mundkur urged lawmakers "to recognize the need to carefully balance competing demands for FDA resources to prevent the increased emphasis on foreign inspections from unintentionally

*(See [Globalization](#), Page 2)*

## CGPA: Proposed Patent Rule Changes Could Cost Canadians

Proposed amendments to Canada's drug patent rules would force consumers and taxpayers to pay monopoly prices on prescriptions for longer than they should, the Canadian Generic Pharmaceutical Association (CGPA) says.

The association, which represents generic drugmakers, made the statement last week after the Canadian government published draft amendments to the *Patented Medicines (Notice of Compliance) Regulations* of Canada's Patent Act in *Canada Gazette*, its official newspaper.

An analysis accompanying the bill says the purpose of the amendments is to ensure that patents protected under the regulations prior to 2006 — grandfathered patents — continue to have protection until their expiration.

*(See [Patent Rule](#), Page 4)*

## ASK THE EXPERT

Earlier this year, the U.S. Court of Appeals for the Federal Circuit ruled that Caraco could challenge a patent even after the brand company grants a covenant not to sue. In the second of a two-piece series, *Generic Line* asked Chad Landmon, a partner with the law firm Axinn, Veltrop & Harkrider, to explain the ruling and what companies can learn from it. He also discusses the ongoing implications from two declaratory judgment cases from last year.

*Why did the court rule that a generic drug-maker had the right to sue in Caraco Pharmaceutical v. Forest Laboratories?*

In *Caraco*, the appeals court ruled that a generic drug applicant could bring a declaratory judgment action to challenge a brand company's patent after the brand company granted a covenant not to sue. Specifically, the court determined that Caraco's right to market a generic version of Forest's Lexapro (escitalopram oxalate) created a legal controversy because the product patent at issue was listed in the Orange Book and was the basis for Ivax's — another generic maker's — 180-day generic exclusivity period. The court held:

If Caraco is correct that its generic drug does not infringe Forest's '941 patent, then it has a right to enter the generic drug market, and its exclusion from the generic drug market by Forest's actions is a sufficient Article III injury-in-fact. Moreover, the fact that Forest's actions can only exclude Caraco from the drug market in the context of the Hatch-Waxman framework does not render Caraco's injury any less "concrete, actual or imminent."

The court went on to find that Caraco's injury flowed directly from Forest's action in listing the patent in the Orange Book. Moreover, the court determined that Caraco's injury could be redressed by a declaratory judgment of non-infringement because that decision, coupled with a decision on another patent listed in the Orange Book, would trigger Ivax's exclusivity period, allowing Caraco to obtain final FDA approval and enter the market.

*What did Judge Friedman say in his dissenting opinion?*

Judge Friedman dissented from the majority opinion, asserting that there was no controversy between the companies because Forest had granted a covenant not to sue. In a typical declaratory judgment action, the potential infringer seeks to protect itself from a subsequent judicial finding that it is liable for patent infringement damages. Caraco, however, faced "no such danger or possibility," Friedman wrote.

Judge Friedman found that Caraco's alleged controversy, which was designed to trigger the first filer's exclusivity period, was "highly speculative and conjectural" in that there was no certainty that Caraco would prevail in its non-infringement claim. He also stated that Caraco's argument may be improperly based on the assumption that the exclusivity period would not begin

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until the first filer commenced marketing or an appellate court decision against the patent.

*What might generic drugmakers do as a result of the Caraco ruling?*

The Federal Circuit's decision will encourage an increasing number of declaratory judgment patent challenges by generic applicants. In particular, ANDA applicants that are subject to a first filer's exclusivity period will be encouraged to bring declaratory judgment actions in order to trigger the exclusivity period or effectuate a forfeiture of the exclusivity period as provided for by the Medicare Modernization Act.

Prior to the Federal Circuit's decision, NDA holders could simply refrain from filing suit against later ANDA filers when the first filer was precluded from going to market, either by a court decision of patent infringement against the first filer or a settlement agreement in which the first filer agreed to a delayed entry date. Now, even if a brand company grants the later ANDA challenger a covenant not to sue, the ANDA filer will be able to maintain the declaratory judgment action, potentially obtaining a court decision against the patent.

*Can you explain how last year's Supreme Court decision in MedImmune v. Genentech and the Federal Circuit's ruling in Teva Pharmaceuticals v. Novartis changed the declaratory judgment doctrine for drug patent cases?*

The Supreme Court's decision in *MedImmune* and the Federal Circuit's decision in *Teva* set the stage for the *Caraco* decision by liberalizing the standards for standing in declaratory judgment actions. In a footnote in *MedImmune*, the Supreme Court took the first step by rejecting the Federal Circuit's "reasonable apprehension of suit" test, which had been employed by courts to dismiss declaratory judgment actions in which the generic firm could not prove that it had a reasonable apprehension of being sued by the brand company.

In *Teva*, the Federal Circuit followed the Supreme Court's lead and found a justiciable

controversy where several patents were listed in the Orange Book but the brand company brought suit on only one of the patents.

By removing the "reasonable apprehension of suit" requirement, the Supreme Court has opened the door for an increasing number of declaratory judgment actions. The *Teva* decision makes such actions particularly likely to survive a challenge to the court's subject matter jurisdiction where patents are listed in the Orange Book. The liberalization of the standard for declaratory judgment jurisdiction will certainly lead to an increased number of such actions by ANDA filers.

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**Patent Rule, from Page 1**

According to CGPA, the changes would allow brand companies to list patents irrelevant to their products and get injunctions preventing Health Canada's approval of generic versions. The association also said the rules would override a Nov. 3, 2006, Canadian Supreme Court ruling that effectively stopped the practice of evergreening.

"The term 'evergreening' captures a variety of strategies by brand-name drugmakers, all involving abuse of the automatic 24-month injunction under the *Regulations*, to extend their market exclusivity beyond the expiry of their basic 20-year patent on a drug," Jean-Guy Goulet, the past chairman of CGPA, said.

The proposed amendments would prohibit the Health Minister from deleting patents submitted prior to June 17, 2006, from the patents register and from refusing to add a patent solely because it is not relevant to a supplement to a new drug submission. They also would prevent generic manufacturers from asking for a dismissal of a prohibition application because the grandfathered patent does not meet listing requirements in place prior to June 17, 2006.

The government is soliciting comments for 15 days, a shorter time period than usual. The *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations* is available at [canadagazette.gc.ca/partI/2008/20080426/html/regle4-e.html](http://canadagazette.gc.ca/partI/2008/20080426/html/regle4-e.html). — Elizabeth Jones