Saab to Appeal Court's Denial

By Katarina Gustafsson And Christina Zander

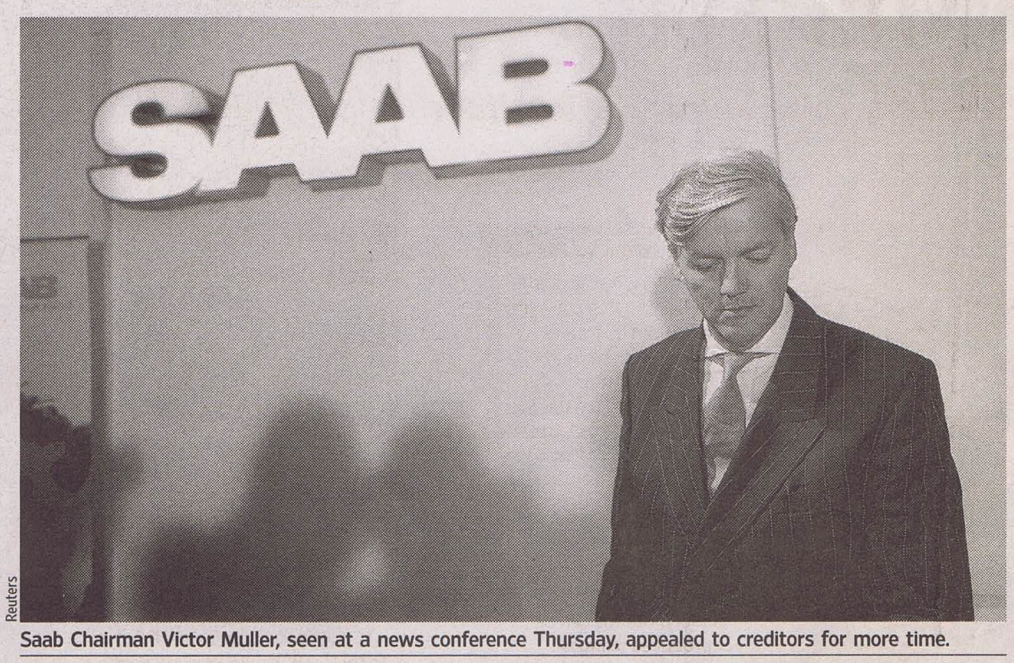
STOCKHOLM—Saab Automobile AB said it would appeal a Swedish court's refusal to grant it protection from creditors. The court ruling clears the way for labor unions representing unpaid workers to petition for bankruptcy and reclaim wages.

The troubled car maker had sought protection in a last-ditch attempt to buy time to secure funding, after struggling with its finances for months and halting production in April.

In its ruling, Vanersborg district court said on Thursday that Saab's application didn't fulfill the legal requirements for protection from its creditors, and it questioned the viability of deals the company had signed with two Chinese companies to obtain financing. Saab's application, which was submitted Wednesday, is similar to a Chapter 11 bankruptcy-court reorganization filing in the U.S.

Saab is disappointed in the ruling and expects its appeal to be heard in a week, said Victor Muller, Saab's chairman and the chief executive of Saab's owner, Netherlands-based **Swedish Automobile** NV.

Saab in recent months had tried to resolve its funding needs by signing agreements with the two Chinese companies to help manufacture and sell cars in China. The deals have been pending approval by regulators in China and Sweden, leaving the company short of cash. It sought bankruptcy protection to give more time for regulators.



Reuters

Saab Chairman Victor Muller, seen at a news conference Thursday, appealed to creditors for more time.

But the court said it is unclear if and when the Chinese deals would be approved. It also questioned the car maker's ability to solve its liquidity crisis and continue operations. The company's lengthy production shutdown had led to a loss of customer and dealer goodwill and caused damage to the Saab brand in the marketplace, the court said.

"It's a tough decision to make, but history shows that where one company disappears, others will sprout eventually," Chief District Court Judge Gunnar Krantz said.

Darko Davidovic, a lawyer for blue-collar labor union IF Metall, said a bankruptcy filing by the company would be better than a bankruptcy petition by IF Metall. The union petition would potentially take longer, he said.

If Saab had been granted protection from creditors, it would have been able to use the Swedish state's salary guarantee to pay wages and would have had more time to sort out its finances.

However, the union will likely proceed with a petition for a bankruptcy, as the workers can only seek state unemployment benefits if they petition for the bankruptcy of their employer.

"We have no choice," Mr. Davidovic said. "We can't play around with our members' wages."

The unions have called meetings to consider a bankruptcy petition. If agreed, a petition could be filed to the Vanersborg district court.

In its ruling, the court also made a point of noting that a previous Saab Automobile reorganization overseen by a court two years ago had failed.

"It was, of course, significant that there has already been a substantial reorganization a few years ago that was not successful," District Court Judge Patrick Baerselman said.

Saab previously won protection from its creditors in February 2009 after then-parent General Motors Co. said it would cut ties with the company following two decades of losses.

In its application, the Swedish car maker said it would have to consider filing for bankruptcy, effectively ending its efforts to resume auto production, if it wasn't granted protection from its creditors.

On Thursday, Mr. Muller said the court's ruling leaves Saab "completely unprotected," as all stakeholders could request the company be put into bankruptcy. Mr. Muller appealed to all stakeholders to "hold their horses," and not take any immediate action that would jeopardize its future. "Much to our surprise and definitely to our disappointment, the court decided to rule against the application for bankruptcy. Now we move onto plan C, which is to appeal," Mr. Muller said.

Panel Calls For More Surgical Mesh Trials

By Jennifer Corbett Dooren

WASHINGTON—A federal ad
visory panel on Thursday calle
for more clinical studies an
tougher regulation of certai
surgical mesh products used t
treat pelvic organ prolapse, a
often painful condition that a
fects thousands of women.

The Food and Drug Adminis
tration panel backed plans b
the agency to require premarke
approval studies for new mes
products when used in a specif
type of procedure to repair o
gan prolapse.

The mesh products, which ar
made by several companies in
cluding **C.R. Bard** Inc., **Bosto
Scientific** Corp. and **Johnson
Johnson**, are currently reviewe
under an FDA device-clearanc
process that doesn't require pr
clinical tests in patients.

FDA officials said existin
products will be allowed to sta
on the market. The panel als
agreed with FDA plans to see
postmarket studies of existin
products.

The FDA is proposing tha
mesh products that are inserte
through the vagina be moved t
the highest-risk, Class III FD
category of medical devices. Thi
requires companies to conduc
clinical trials in people and the
submit an application seekin
FDA approval, similar to th
mechanism required for drugs

The advisory panel didn't tak
a formal vote on whether to re
classify the devices. But a majo
ity of the panel of non-FDA me
ical experts said they supporte
the agency's proposal. The FD
isn't required to follow it
panel's advice but usually doe

The companies have asked th
FDA to keep the products a
Class II, but said they agree
with the need to conduct pos
market clinical studies.

The devices are currently re
viewed under the so-calle
510(k) process which allow
companies to obtain FDA clea
ance for devices without co
ducting clinical trials if they ca
show a product is "substantiall
equivalent" to an existing devic

*—Shirley S. Wang contribute
to this articl*

FDA Panel Backs Warfarin Alternative Xarelto

By Thomas M. Burton

A Food and Drug Administration advisory committee recommended approval of a major new anticoagulant drug for stroke prevention, rejecting an FDA staff analysis that found flaws in the study of the medicine.

The drug, Xarelto, from **Johnson & Johnson** and **Bayer** AG, is among the first of a new class that might replace decades-old warfarin to prevent strokes among patients with a type of faulty heartbeat.

Wall Street and the drug industry hope the class of drugs, also including **Boehringer Ingelheim** GmbH's Pradaxa and Eliquis from **Bristol-Myers Squibb** Co. and **Pfizer** Inc., will generate billions of dollars of sales a year. The FDA approved Pradaxa last year. An application for approval of Eliquis is expected this year.

The panel's vote was 9-2 with one abstention. The FDA doesn't have to follow the advice of its outside panels but usually does. Xarelto is an unusual case because a strong majority of the panel disagreed with the FDA staff's conclusions.

In a report earlier this week, the FDA's staff reviewer said warfarin wasn't skillfully used in the research and that may have made Xarelto look better. The report advised against approval of Xarelto for stroke prevention.

Xarelto was recently approved to prevent clotting after certain orthopedic operations, but approval for stroke prevention would give J&J and Bayer access to a far bigger group of patients.

The faulty heartbeat in question is called atrial fibrillation, and millions of patients have it. They're susceptible to strokes, and anticoagulants are designed to prevent future strokes. Warfarin has been used in that role for half a century, but it has drawbacks, including the need for doctors to measure its levels in the bloodstream frequently.

The new class of drugs carries no such requirement, but it raises another question: whether America and the world will pay for a drug costing several dollars a day in place of an effective one costing pennies a day.

The drug "is a step in the right direction, but the benefit, even among thousands of patients, is tiny," said cardiologist Eric J. Topol, chief academic officer at Scripps Health in LaJolla, Calif. "Can we afford this now? We're committing people for the rest of their lives for maybe $5, $6 or $7 a day."

The drug's makers say it will be more convenient for patients and reduce side-effect risks.

"We believe that our data show the drug should be available for all patients with risk factors" for stroke, said Peter M. DiBattiste, head of J&J's cardiovascular research, after the vote.

An FDA reviewer, Martin Rose, told the panel Thursday that too many hospitals in the study didn't do a good enough job of ensuring that patients had a therapeutic amount of warfarin.

Robert M. Califf, vice chancellor at Duke University Medical Center and a principal investigator in the J&J-Bayer trial, said patients on the drug got results that were "noninferior," or statistically comparable to those on warfarin treatment. The study included 14,264 patients in 45 countries taking either Xarelto or warfarin. Dr. Califf also said that, with Xarelto, "there was a substantial reduction" in brain hemorrhages and other fatal bleeding.