

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

BASF AGRO B.V., ARNHEM (NL),
WADENSWIL BRANCH and BAYER
S.A.S.,

Plaintiffs,

v.

MAKHTESHIM AGAN OF NORTH
AMERICA, INC., and CONTROL
SOLUTIONS, INC.,

Defendants.

C.A. No. 1:10-cv-00276-WO-LPA

NOTIFICATION

Defendants Makhteshim Agan of North America, Inc. and Control Solutions, Inc. (collectively, “Defendants”) are filing this notification to inform the Court that due to a one-time mistake, two lots of TaurusTM SC product – Lot Nos. 23569 and 23795 – contained fipronil technical material which was not made by the Currently Intended Process, and were sold in the United States in violation of the Consent Judgment entered by this Court on October 27, 2010. (Doc. No. 46.) Defendants only recently became aware of this error upon investigating the allegations made in BASF’s complaint for patent infringement filed in the U.S. District Court for the Northern District of Georgia on March 19, 2013. In particular, Defendants became aware of the lot being accused of infringement in Georgia (Lot no. 23569) upon reviewing BASF’s production of documents on April 3, 2013 in connection with the currently pending contempt motion.

Defendants promptly initiated an investigation to determine the batches of fipronil technical material that were incorporated in the accused lot. It was not until April 12, 2013 that Defendants were able to identify the source of the fipronil technical material that was used in the accused lot and discovered that a mix-up in the source of the fipronil technical material was made. Defendants continued their investigation to determine what had happened and are informing the Court of the preliminary findings of that investigation.¹

I. Executive Summary

As set forth in detail below, Defendants agreed to manufacture fipronil according to the Currently Intended Process, and indeed, Defendants have manufactured and continue to manufacture fipronil according to the Currently Intended Process at Makhteshim Chemical Works' ("MCW") plant in Israel. In early 2012, due to a manufacturing issue at MCW's formulation plant, Defendants had to find an alternate location to formulate the TaurusTM products. The plan had always been to transfer the formulation of the TaurusTM product from Israel to Control Solutions, Inc.'s ("CSI") facility in Texas, but unfortunately CSI did not yet have the formulation capability up and running in early 2012. Accordingly, a decision was made to formulate the product at MAI's subsidiary located in Colombia, South America – for one time only – as a stop gap measure until CSI's formulation capability was up and running. Consistent with that

¹ Although TaurusTM Lot No. 23795 has not been accused of infringement, Defendants' investigation has revealed that this lot also contained fipronil that was not made according to the Currently Intended Process and Defendants are bringing this to the Court's attention as well.

decision, fipronil technical material that had been made according to the Currently Intended Process at MCW's plant in Israel was shipped to the Colombian subsidiary. Although the details are still under investigation, instead of using the fipronil that it had been sent from MCW in Israel (made according to the Currently Intended Process), it appears that the Colombian subsidiary used fipronil that it had in stock from an alternate source to formulate the TaurusTM product. The TaurusTM SC product containing fipronil from an alternate source was then shipped to CSI and sold in the United States during the latter portion of 2012 and the beginning of 2013.

Defendants were unaware that this mix-up had occurred until investigating the lot that was accused of infringement in BASF's Georgia complaint. Defendants have conducted an audit on all the lots of the TaurusTM SC product and can confirm that all lots, with the exception of the two lots formulated by the Colombian subsidiary, were made with fipronil manufactured by the Currently Intended Process. Defendants will not formulate any other lots at the Colombian subsidiary for the U.S. market prior to expiration of U.S. Patent No. 5,618,945. In addition, as set forth below, Defendants have taken remedial steps to remove product from Lot nos. 23569 and 23795 from the market to the extent any stock still remains in the inventory of Defendants' distributors. This was a one-time event, an unfortunate mistake that will not be repeated.

II. Detailed Summary

As BASF was informed early in the case, Defendants' fipronil is manufactured following the Currently Intended Process in the following manner: the final intermediate

in the synthesis of fipronil made according to the Currently Intended Process is shipped to Israel and is then converted into fipronil technical material by MCW in Israel. The fipronil technical material is then formulated into TaurusTM SC product either by MCW in Israel or by CSI in the United States. *See* Defendants Response to Interrogatory No. 5, served July 14, 2010, attached as Exhibit A.² It had always been Defendants' plan to begin the formulation of the TaurusTM SC product at MCW in Israel and then to transfer the formulation of the TaurusTM SC product to CSI in Texas once CSI had the capability to do so.

All TaurusTM lots that were sold in the United States prior to August 7, 2012, including the lots that are the subject of the currently pending contempt proceeding, contained fipronil that was manufactured according to the Currently Intended Process and were formulated at MCW in Israel. In early 2012, due to a temporary manufacturing issue, MCW was unable to formulate the fipronil technical material into the TaurusTM SC product at its Beer Sheva, Israel plant. Needing another location for the formulation of the TaurusTM SC product, Makhteshim Agan Industries ("MAI") asked CSI whether it was ready to formulate the fipronil technical material into the TaurusTM product. CSI informed MAI that it was not yet prepared to do so. *See* email attached as Exhibit B. Accordingly, an interim decision was made to formulate the Israeli-made fipronil technical material into the TaurusTM SC product at a subsidiary of MAI located in

² Defendants have filed a motion to seal the exhibits, which contain confidential business information, and filed the exhibits under seal. However, where appropriate, redacted versions of the exhibits are being filed publicly as well.

Colombia, South America. The Colombian subsidiary also formulates other fipronil-containing products for MAI, using fipronil technical material that is received directly from other sources for sale in countries outside the U.S. which have different patent protection than the U.S.

On February 13, 2012, an order was placed by Irvita Plant Protection N.V. (“Irvita”) on behalf of CSI for 50,000 liters of formulated TaurusTM SC product. *See* 2/13/2012 Jobbing Order attached as Exhibit C.³ As indicated in the order, the formulation of the fipronil technical material was to be carried out at the Colombian subsidiary. After discussions with the Colombian subsidiary regarding the technical specifications of the TaurusTM product and informing the Colombian subsidiary that the TaurusTM material needed to be formulated using fipronil made and shipped from MCW in Israel, a shipment of 4,050 kg of fipronil technical material made using the Currently Intended Process was shipped from MCW, Israel to the Colombian subsidiary on February 29, 2012. *See* shipment information attached as Exhibit D. Just before the fipronil technical material was shipped to the Colombian subsidiary, the quantity of technical material to be shipped, 4,050 kg, was determined to be insufficient to formulate 50,000 liters of TaurusTM (a 50,000 liter order would require 4,550 kg of fipronil technical material, not 4,050 kg). *See* email attached as Exhibit E. Accordingly, on March 2, 2012, Irvita amended the order it had placed for CSI – to correct the math –

³ As indicated in Defendants’ Response to Interrogatory No. 5, attached as Exhibit A, Irvita Plant Protection N.V. is responsible for the commercial logistics relating to the fipronil technical material and fipronil-containing products.

reducing the amount of requested formulated TaurusTM material from 50,000 liters to 44,000 liters. This order was to be filled using the 4,050 kg of fipronil technical material shipped from MCW, Israel to the Colombian subsidiary, which had been manufactured using the Currently Intended Process. *See* Amended Jobbing Order attached as Exhibit F.

Although the investigation of the facts is still ongoing, it appears that, even though it had received the amended order, the Colombian subsidiary may not have realized that the quantity of the order had been changed to 44,000 liters, and from March 12, 2012 to March 15, 2012, the Colombian subsidiary conducted a **single** campaign in which it formulated 50,000 liters of Taurus product. Despite being told that the formulation for the United States must use the fipronil technical material sent by MCW in Israel, personnel at the Colombian subsidiary mistakenly formulated the Taurus product using the incorrect fipronil technical material – material from another supplier. Defendants’ investigation into the circumstances surrounding this mistake is ongoing. Needless to say, however, the Colombian subsidiary will not again formulate any Taurus product for the U.S. market until after the ‘945 patent expires. CSI’s Texas facility is up and running and has been formulating the Taurus product since July 2012 using fipronil technical material from MCW’s Israel plant, made by the Currently Intended Process.

CSI assumed that the fipronil technical material in the shipments of 50,000 liters it had received from the Colombian subsidiary⁴ originated from MCW in Israel – as CSI

⁴ Due to a labeling issue, the shipments were delayed and ultimately supplied to CSI on July 16, 2012 and August 9, 2012. Upon receiving the shipments of formulated material, CSI repackaged the material into bottles which were sold as TaurusTM lot nos. 23569 and 23795:

understood that the Colombian subsidiary was being sent the MCW fipronil technical material to formulate, and had no reason to think otherwise. CSI was unaware of the mix-up of the fipronil technical materials. MCW and MAI were also unaware of the mix-up of the fipronil technical material as they sent the MCW fipronil technical material to the Colombian subsidiary with the order to formulate TaurusTM SC product and expected that the TaurusTM SC product would be made with the fipronil technical material made by MCW Israel using the Currently Intended Process. The mix-up of the fipronil technical materials was only discovered as a result of the investigation conducted after BASF filed its complaint in Georgia and Defendants' counsel learned of the lot number which formed the basis of the allegations set forth in that Georgia complaint.

Since learning of this mistake, Defendants have checked and determined that they no longer have any stock of TaurusTM Lot nos. 23569 or 23795 in their inventories. In addition, CSI has asked its distributors who may still have some inventory of TaurusTM Lot nos. 23569 or 23795 to stop selling those lots and to return the products from those lots to CSI. Indeed, as of this date about 25% of these lots has been recalled from distributors and efforts are continuing to see if any other inventory remains that can be recalled.⁵

Lot no. 23569 was packaged in August 2012 from the formulated material received from the Colombian subsidiary; Lot no. 23795 was packaged in February 2013 and consisted of a blend of the formulated material received from the Colombian subsidiary and material that had been formulated at MCW using fipronil that had been manufactured according to the Currently Intended Process.

⁵ Sales of TaurusTM Lot no. 23569 did not begin until after August 7, 2012 and sales of TaurusTM Lot no. 23795 did not begin until February 2013.

In short, all the lots sold which contained fipronil technical material originating from an alternate source were from a **single** production campaign at the Colombian subsidiary which took place between March 12 and March 15 of 2012. The formulation at the Colombian subsidiary was necessitated because MCW had a temporary manufacturing issue at its Israel formulation plant and CSI was not yet ready to start formulating in Texas. Defendants will not formulate any TaurusTM SC product at the Colombian subsidiary prior to the expiration of U.S. Patent No. 5,618,945.

All future formulation of fipronil technical material for the U.S. market will be performed at CSI in Texas or MCW in Israel and will use the Israel fipronil technical material made by the Currently Intended Process until after expiration of the '945 patent. Thus, this one-time mistake will not happen again as the MAI subsidiary in Colombia will not be involved. There has been and will be no fipronil technical material in the inventory at MCW, Israel other than that prepared at MCW's plant in Israel using the Currently Intended Process. This will ensure that going forward all fipronil technical material coming into the United States to CSI will be made by the Currently Intended Process.

In view of the above, Defendants request a status conference with the Court in order to determine how the Court would like to proceed.

This the 22nd day of April, 2013.

SMITH MOORE LEATHERWOOD LLP

/s/ Gregory G. Holland
Gregory G. Holland (NCSB No. 19069)
300 North Greene Street, Suite 1400
Greensboro, NC 27401
greg.holland@smithmoorelaw.com
phone: (336) 378-5200
fax: (336) 378-5400

Of counsel:

GOODWIN PROCTER LLP

Marta E. Gross
Joseph B. Crystal
Timothy J. Doyle
The New York Times Building
620 Eighth Avenue
New York, NY 10018
mgross@goodwinprocter.com
jcrystal@goodwinprocter.com
tdoyle@goodwinprocter.com
phone: (212) 813-8800
fax: (212) 355-3333

Attorneys for Defendants
Makhteshim Agan of North America, Inc.,
and Control Solutions, Inc.

April E. Abele
Three Embarcadero Center
San Francisco, CA 94111-4003
aabele@goodwinprocter.com
phone: (415) 733-6000
fax: (415) 677-9041