ILLINOIS POLLUTION CONTROL BOARD
April 7, 2005

WALLACE PHARMACEUTICALS (n/k/a MEDPOINTE PHARMACEUTICALS),	)	
Petitioner,	)	
v.	)	PCB 02-207 (Variance - Air)
ILLINOIS ENVIRONMENTAL PROTECTION AGENCY,	)	
Respondent.	)	

SUPPLEMENTAL OPINION AND ORDER OF THE BOARD (by J.P. Novak):

The Board today terminates, at the parties' request, a September 19, 2002 variance from the volatile organic material (VOM) emission control requirements of 35 Ill. Adm. Code 215.482(a). The variance was granted subject to conditions, and is not by its terms due to expire until December 31, 2006. Wallace Pharmaceuticals v. IEPA, PCB 02-207 (Sept. 19, 2002).

On March 10, 2005, the Illinois Environmental Protection Agency (Agency) and petitioner, Wallace Pharmaceuticals, now known as MedPointe Pharmaceuticals, and (MedPointe), filed a "joint motion to withdraw variance" (Motion). The parties report that the variance is no longer necessary, and that MedPointe wishes relief from the conditions contained in the variance.

THE VARIANCE

The following summary of MedPointe's process is drawn from the Board's opinion and order granting the variance. MedPointe manufactures pharmaceutical tablets at its facility in Decatur, Macon County. During Wallace's production process, several of the tablet products use a wet granulation process. Two forms of wetting agents are used, water and the VOM at issue here: denatured ethanol. When ethanol is used as the wetting agent, it is evaporated during the drying cycle, resulting in VOM emissions from the dryers. MedPointe used five dryers in this process. In its May 2002 petition, MedPointe stated that it planned to increase production in October 2002, which would make its five dryers newly-subject to increased VOM control requirements. Wallace, PCB 02-207, slip op. at 1-2.

MedPointe's VOM emissions would be regulated under 35 Ill. Adm. Code 215.482(a) if MedPointe's drying process exceeds the applicable thresholds of Section 215.480(a). Section 215.480(a) regulates VOM emission sources at pharmaceutical manufacturing plants whose emissions exceed 15 lbs./day and 2.5 tons/year or whose emissions are less than 2.5 tons per year

(tpy) but more than 100 lbs. per day. 35 Ill. Adm. Code 215.480(a). Section 215.482(a) requires at least 90% reduction in VOM emissions from each unit. 35 Ill. Adm. Code 215.482(a).

MedPointe expected the accelerated production and increased demand from three new product lines beginning in October 2002 to cause the facility to exceed the thresholds of Section 215.480(a) and become subject to the Section 215.482(a) control requirements. MedPointe requested the variance to allow it sufficient time to evaluate and implement potential options for controlling VOM emissions from its dryers. During the variance period, MedPointe proposed to comply with suggested alternate VOM emission limits of 5 tpy of VOM per dryer, or up to a total of 25 tpy. Wallace, PCB 02-207, slip op. at 2-3.

The Agency recommended granting the variance. Environmental impact was not expected to be substantial in an area where there had been no exceedences of the ozone standard for the previous three reporting years. Without relief, the Agency argued, MedPointe would be forced to shut down its production and lay off employees. Wallace, PCB 02-207, slip op. at 3, 6.

The Board found that denial of variance would impose an arbitrary or unreasonable hardship. Under all of these circumstances, the Board concluded that MedPointe

> has demonstrated that denial of variance would impose an economic hardship. Even with increased production, [MedPointe's] VOM emissions will have additional controls, and its addition to the VOM emissions in the area will be minimal. Wallace, PCB 02-207, slip op. at 6.

The variance, granted through December 31, 2006, imposed several conditions. The variance limited emissions from each of the five dryers to 5.0 tons per year of VOM emissions, and additional daily limits were imposed on two of the dryers. Other conditions required that various research, testing, and evaluation for control technology be accomplished by various times certain, that regular progress reports be filed. Wallace, PCB 02-207, slip op. at 7-8.

THE JOINT MOTION

In their March 10, 2005 joint motion, the parties report that

> the products that involved the use of VOM, that were the subject of the variance, have all but ceased production. Production at the facility has instead shifted to different products that do not involve VOM. Based on this shift in its operations, MedPointe represented that it has been emitting VOM far below the thresholds in 35 Ill. Adm. Code 215.480(a) for the duration of the variance . . . . Motion at 3-4.

The parties suggest that the variance order does not provide clear guidance under the current situation, where MedPointe's reported plantwide annual emissions for 2002 (6.87 tpy) and 2003 (1.2 tpy) are well below the 12.5 tpy (2.5 tpy x 5 dryers) applicability threshold in 35 Ill. Adm. Code 480(a). To eliminate any question as to whether MedPointe must continue to submit progress reports, the parties suggest "the variance should simply be withdrawn." The parties believe that variance withdrawal "would have no impact on Macon County's attainment status,

and if anything, will benefit the environment by eliminating the previously allowed increase in daily and annual VOM emissions from the facility." Motion at 4.

BOARD ANALYSIS AND CONCLUSION TO TERMINATE MEDPOINTE'S ADJUSTED STANDARD

The Board appreciates the parties' difficulty in determining the precise nature of Medpointe's obligations under the variance, given this unanticipated situation. Production of the products giving rise to the need for the variance has all but ceased, according to the parties, rather than increasing steadily as anticipated in 2002.

After careful consideration, the Board finds that termination of the variance is the appropriate action, as MedPointe can no longer justify the need for the variance. As the parties have suggested no other more appropriate date, the Board terminates MedPointe's variance as of the date of this opinion and order. For any enforcement purposes, then, MedPointe's variance from 35 Ill. Adm. Code Section 218.482(a) was effective from September 19, 2002 through April 7, 2005.

This supplemental opinion constitutes the Board's supplemental findings of fact and conclusions of law.

ORDER

At the parties' request, effective April 7, 2005, the Board terminates the September 19, 2002 variance granted in this docket from 35 Ill. Adm. Code Section 218.482(a) for five dryers at the Wallace Pharmaceuticals (n/k/a MedPointe Pharmaceuticals) facility in Decatur, Macon County.

IT IS SO ORDERED.

Section 41(a) of the Environmental Protection Act provides that final Board orders may be appealed directly to the Illinois Appellate Court within 35 days after the Board serves the order. 415 ILCS 5/41(a) (2002); *see also* 35 Ill. Adm. Code 101.300(d)(2), 101.906, 102.706. Illinois Supreme Court Rule 335 establishes filing requirements that apply when the Illinois Appellate Court, by statute, directly reviews administrative orders. 172 Ill. 2d R. 335. The Board's procedural rules provide that motions for the Board to reconsider or modify its final orders may be filed with the Board within 35 days after the order is received. 35 Ill. Adm. Code 101.520; *see also* 35 Ill. Adm. Code 101.902, 102.700, 102.702.

I, Dorothy M. Gunn, Clerk of the Illinois Pollution Control Board, hereby certify that the above supplemental opinion and order was adopted on the day of April 7, 2005, by a vote of 4-0.

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board