KING & SPALDING

Client Alert

Environmental, Health & Safety Practice

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Clean Air Act Enforcement in the Pharmaceutical Industry - Major Pharmaceutical Company to Pay $2.2 Million to EPA to Resolve Violations

On June 28, 2013, King Pharmaceuticals LLC ("King") agreed to pay a $2.2 million fine and take measures to comply with the Clean Air Act (CAA) to resolve alleged failures to comply with major source requirements at its pharmaceutical manufacturing facility located in Bristol, Tennessee.

The settlement requires the facility to demonstrate compliance with CAA National Emission Standards for Pharmaceuticals Production (PharmaMACT regulations) and to apply for a Title V permit. The EPA's PharmaMACT regulations impose "Maximum Achievable Control Technology" (MACT) standards, which are industry-specific measures that must be implemented to control hazardous air pollutants.

According to Robert G. Dreher, Acting Assistant Attorney General for the Justice Department's Environment and Natural Resources Division, the "significant civil penalty should send a strong signal to the pharmaceutical industry regarding our commitment to enforce PharmaMACT."

In its enforcement case, EPA and the State of Tennessee alleged that King:

1) failed to comply with its construction permit application resulting in the failure to control certain emission sources with the air pollution control device;

2) failed to conduct a valid performance test of the air pollution control device as required by its construction permit;

3) failed to operate the control device as required by its operating permit;

4) failed to achieve the destruction efficiency required in its construction permit application; and,

Because the resulting emissions exceeded the major source threshold, the facility also:

1) violated its permit emission limits; and

2) violated Section 112 of the CAA and the National Emission Standards for Hazardous Air Pollutants (NESHAP) for pharmaceutical production by failing to obtain an operating permit.

King began pharmaceutical manufacturing operations at the Bristol facility in 1993. The alleged violations were discovered during a May 2006 inspection and subsequent investigation by EPA and the State of Tennessee. King was acquired by Pfizer Inc. in 2011, becoming a wholly owned subsidiary of Pfizer. According to Pfizer, the events underlying the enforcement action all occurred prior to its acquisition of King.

EPA's enforcement action highlighted in this Client Alert signals EPA's interest in targeting Pharma manufacturers. It also serves as a reminder that identification of noncompliant conduct as early as possible in acquisition due diligence gives parties to a transaction a strategic advantage. We look forward to working with clients on their strategies for managing the implications of EPA's CAA enforcement initiatives.