A NOT-SO-SILVER LINING: THE NINTH CIRCUIT VACATES EPA'S CONDITIONAL APPROVAL OF A NANOSILVER PESTICIDE USED IN MANUFACTURING "ANTIMICROBIAL" CONSUMER PRODUCTS

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SUMMARY

Do you manufacture, distribute or sell products such as trash cans, cell phones, computers, furniture, watch bands, uniforms, sportswear, or office supplies that have labels claiming that the products are “antimicrobial” or “antibacterial”? If so, under an opinion issued this week by the U.S. Court of Appeals for the Ninth Circuit, the ability to manufacture, distribute, or sell products labeled as “antimicrobial” or “antibacterial” may now be limited if those products use NSPW-L30SWS (“NSPW” or “Nanosilva”) as the antimicrobial agent.

On May 30, 2017, a Ninth Circuit panel “vacated in whole” the U.S. Environmental Protection Agency's (“EPA” or the “Agency”) conditional registration of NSPW under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), a liquid nanosilver product widely used in the manufacture of textiles and plastics for its antimicrobial properties.[1] Because the Court's decision results in an immediate revocation of the conditional registration for NSPW, products containing NSPW that make antimicrobial claims may no longer be supported by an active FIFRA registration. As a result, manufacturers, distributors and sellers of such products should consider reviewing immediately whether their products that contain NSPW include any antimicrobial claims, and if so, whether those products can continue to include such claims following the revocation of NSPW's conditional registration.

BACKGROUND AND ANALYSIS

FIFRA Conditional Registrations

FIFRA governs the sale, use and distribution of pesticides, which includes products that claim pesticidal properties, often using the term “antimicrobial.” Generally, it requires that pesticides must be registered with EPA before being sold or distributed. Under FIFRA, pesticides may be registered by EPA either on an unconditional or a conditional basis. Specifically, EPA can grant an unconditional registration only when an applicant submits

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sufficient data to allow EPA to evaluate the environmental risks of the product and make certain additional findings.[2]

In contrast, where an applicant has not submitted sufficient data to support an unconditional registration, EPA may still issue a conditional registration where the Agency determines that, although a registration decision can be made, further data, studies, or action by the registrant are required by EPA. However, before EPA can grant a conditional registration, FIFRA requires that the Agency must first make two separate findings: (1) that "the use of the pesticide during [the period of the conditional registration] will not cause any unreasonable adverse effect on the environment" and (2) that "use of the pesticide is in the public interest."[3]

Use of Nanosilver as a Pesticide

"Conventional" silver has long been recognized for its antimicrobial properties and is listed as the active ingredient in a number of currently registered pesticides. More recently, product manufacturers have moved towards nanosilver as an antimicrobial agent in their products, which is a version of conventional silver that has been altered to have a much smaller particle size than conventional silver but still retains the same antimicrobial properties. When incorporated into plastics and textiles, nanosilver can suppress the growth of bacteria, algae, fungus, mold, and mildew, which can cause odors, stains, and deterioration.

Prior to the Court's decision, EPA had granted conditional registrations for two pesticides with nanosilver as the active ingredient: AGS-20 and NSPW. AGS-20 is a powder used in surface coatings or by incorporation into textiles, and EPA approved its conditional registration in December 2011. In 2013, the Ninth Circuit partially vacated the conditional registration of AGS-20, finding that EPA did not satisfy the requirement for determining particular risk concerns requiring mitigation.[4]

In contrast to AGS-20, NSPW is a liquid suspension that can be incorporated into plastics and textiles, and EPA approved its four-year conditional registration in May 2015. Due to its smaller particle size and liquid form, NSPW is used in a wide variety of plastic and textile products, including: carpet, trash cans, mops, window blinds, furniture, baseboards, light switches, plastic decking, toilet seats, shower curtains, tubs, cell phones, computers, plastic components in humidifiers, vacuums, combs, brushes, electric razors, blow dryers, beds, wall coverings, wheelchairs, linens, golf bags, exercise equipment, life preservers, sportswear, nursing uniforms, watch bands, restaurant uniforms, litter boxes, swimming pool equipment, ink pens, portable toilets, office supplies, and luggage.

In conditionally registering NSPW, EPA found that it had a lower application rate (i.e., its application requires less silver) and a lower mobility rate (i.e., its application is less likely to release silver into the environment in detachable quantities) in comparison to conventional silver pesticides.[5] EPA therefore concluded that the use of NSPW has the "potential" to reduce the amount of silver released into the environment, thus supporting its conclusion that use of the pesticide was in the public interest.[6]

The Ninth Circuit's Ruling and its Impact on Manufacturers of Products Containing NSPW

The Ninth Circuit vacated EPA's conditional approval of NSPW. The court started with the premise that conditional registrations should be granted rarely and concluded that EPA failed to adequately support its finding

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that the use of NSPW is in the public interest, as required by FIFRA.[7] Specifically, the Ninth Circuit found that, in order to reach its conclusion, EPA had to make two additional assumptions: (1) that current users of conventional silver pesticides would replace those pesticides with NSPW and (2) that NSPW would not be incorporated into any new products.[8] The court found that EPA did not support these assumptions with substantial evidence, as required by FIFRA, and that the conditional registration was therefore invalid and must be vacated.[9]

This decision has an immediate and substantial impact on manufacturers, distributors, and sellers of products that contain NSPW and make antibacterial or antimicrobial claims based on their use of NSPW, as those products may no longer rely upon the conditional registration of NSPW to make antimicrobial claims regarding their products. In addition, given that EPA is likely to require the submission of additional data before it can consider granting either a conditional or unconditional registration for NSPW, it is unknown whether or when products containing NSPW will be able to make such claims. With that in mind, manufacturers using NSPW, as well as distributors and sellers of products containing NSPW, are likely to review the labels on their products containing NSPW and may well eliminate any antimicrobial claims that relied on the presence of NSPW.

More generally, the Ninth Circuit's decision serves as a cautionary tale to the manufacturers, distributors and sellers of any products relying upon conditional registrations to make antimicrobial or other pesticidal claims that such conditional registrations are more susceptible to challenge — and potential revocation — than products with unconditional registrations. As a result, companies relying upon such registrations often seek to play an active role in any litigation relating to the potential revocation of registrations on which they rely to make antimicrobial or other claims.

Notes:

[1] Natural Resources Defense Council v. EPA, No. 15-72308 (9th Cir. May 30, 2017), http://cdn.ca9.uscourts.gov/datastore/opinions/2017/05/30/15-72308.pdf.

[2] 7 U.S.C. § 136a(c)(5) (listing the findings required for unconditional registration).

[3] 7 U.S.C. § 136a(c)(7)(C).

[4] Natural Resources Defense Council v. EPA, 735 F.3d 873, 886–87 (9th Cir. 2013). More information on the history of this litigation, and more generally with respect to nanosilver and nanotechnology, can be found in: B. David Naidu, Biotechnology & Nanotechnology Regulation ch. 5 (LexisNexis (Matthew Bender) 2017 ed.).

[5] Natural Resources Defense Council v. EPA, No. 15-72308, at *8.

[6] *Id.*

[7] *Id.* at *13, 15.

[8] *Id.* at *18.

[9] *Id.* at *22–23.

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