United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 22, 2013 Decided March 12, 2013

No. 12-5182

HILL DERMACEUTICALS, INC.,
APPELLANT

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:11-cv-01950)

Larry M. Roth argued the cause for appellant. With him on the brief was *Neil P. Di Spirito.*

Cindy J. Cho, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Stuart F. Delery*, Principal Deputy Assistant Attorney General, *Maame Ewusi-Mensah Frimpong*, Deputy Assistant Attorney General, and *Drake Cutini*, Attorney.

William D. Coston, *Martin L. Saad*, and *David D. Conway* were on the brief for intervenor Amneal Pharmaceuticals, LLC in support of appellee.

Before: BROWN, *Circuit Judge*, and EDWARDS and SILBERMAN, *Senior Circuit Judges*.

Opinion for the Court filed PER CURIAM.

PER CURIAM: Hill Dermaceuticals filed a successful new drug application with the FDA in 1988 for a corticosteroid called "Derma-Smoothe." The application included three separate products — body oil, scalp oil, and ear oil drops. In 2011 the FDA approved three abbreviated new drug applications ("ANDAs") submitted by Identi Pharmaceuticals for generic versions of Hill's three products. Hill sued the FDA in the U.S. District Court for the District of Columbia, arguing that the FDA's approval of Identi's products was arbitrary and capricious under the Administrative Procedure Act.[1] The district court granted summary judgment to the FDA, and Hill filed this appeal.

Under the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act, abbreviated drug applications need not include all of the same clinical data as new drug applications.

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[1] Before the district court, Hill sought both declaratory and injunctive relief, seeking to enjoin the FDA from approving Identi's new drugs — which apparently is a common kind of request in these cases. Usually, where a district court reviews agency action under the APA, it acts as an appellate tribunal, so the appropriate remedy for a violation is "simply to identify a legal error and then remand to the agency." *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013) (quoting *N. Air. Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012)). But because preliminary injunctions are expedited, they may sometimes be appropriate in APA cases where time is of the essence — for instance, where a party believes there is an immediate need to prevent a new drug from reaching the market. But any such injunction would need to be limited only to vacating the unlawful action, not precluding future agency decisionmaking.

Rather, ANDA applicants need only identify an approved drug and then "show that the new drug is bioequivalent to the listed drug." 21 U.S.C. § 355(j)(2)(A)(iv).[2] FDA regulations establish that the requirement to submit data showing bioequivalence may be waived where the drug is a solution for application to the skin, has active ingredients in the same concentration and dosage as an approved drug, and "[c]ontains no inactive ingredient or other change in formulation from [an approved drug] that may significantly affect absorption of the active drug ingredient." 21 C.F.R. § 320.22(b)(3). The FDA granted bioequivalence waivers for Identi's body and scalp oil under § 320.22(b)(3) and granted a waiver for Identi's ear drops under 21 C.F.R. § 320.24(b)(6), a catch-all provision allowing waiver under "[a]ny other approach deemed adequate by FDA to . . . establish bioequivalence."

As a preliminary matter, Hill argues that the district court abused its discretion in refusing to consider 21 extra-record declarations that purportedly provide detailed technical information about Hill's products. But of course, it is black-letter administrative law that in an APA case, a reviewing court "should have before it neither more nor less information than did the agency when it made its decision." *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984). The district court did not abuse its discretion in adhering to this well-established principle.

We have recognized a small class of cases where district

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[2] A drug is "bioequivalent" to a listed drug if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses." 21 U.S.C. § 355(j)(8)(B)(i).

courts may consult extra-record evidence when "the procedural validity of the [agency]'s action . . . remains in serious question," *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C. Cir. 1989), but Hill's case does not fall within this narrow set of exceptions. *Esch* has been given a limited interpretation since it was decided, and at most it may be invoked to challenge gross procedural deficiencies — such as where the administrative record itself is so deficient as to preclude effective review. *See Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 514 (D.C. Cir. 2010).

Hill then presents four arguments challenging the FDA's decision to grant bioequivalence waivers, but none have merit. First, appellant argues that its products are not "solutions" under 21 C.F.R. § 320.22(b)(3), so waiver was not allowed under this provision. But the relevant question is whether the *new* drug, not the listed drug, is a solution, and in any event, record evidence amply supports the FDA's conclusion that both products are solutions (for example, the active ingredient in both is dissolved in isopropyl alcohol).

Second, Hill suggests that the FDA improperly approved Identi's scalp oil because the agency had previously stated that the scalp needed to be treated differently from other body skin for the purposes of bioequivalence. But that statement made clear that different testing for the scalp was needed only where the requirements of a waiver were *not* met. Here, the FDA reasonably determined that a waiver was warranted, so appellant's argument is beside the point.

Third, Hill argues that the waiver for Identi's ear drops was improper because Identi omitted two fragrances that Hill had used in its own products. Though these fragrances are inactive ingredients, Hill suggests that their absence would alter the drug's substantive effects. But this is the sort of technical,

scientific question on which deference to agencies is especially warranted. The FDA reasonably concluded — after examining the makeup of Identi's drugs and consulting with multiple divisions within the agency — that the omission of the fragrances would have no expected effect on efficacy or safety.

And fourth, appellant contends that the FDA's approval of Identi's abbreviated applications contained sufficiently numerous and serious inaccuracies to render these decisions arbitrary and capricious. But most of these alleged errors are minor technical mistakes, such as the use of a wrong application number for an Identi product or listing an incorrect date on a prior application, and Hill develops no argument suggesting that the alleged errors resulted in prejudicial treatment or that the agency's ultimate decision would have been any different but for these inaccuracies.

Finally, Hill argues that the FDA should not have approved Identi's drugs because Identi does not use the same labeling as Hill. Specifically, the current labeling for Hill's products states: "The peanut oil used in Derma-Smoothe/FS is tested for peanut proteins through amino acid analysis which can detect the quantity of amino acids to below 0.5 parts per million." Identi, by contrast, states merely that its products include peanut oil refined under U.S. Pharmacopeia-National Formulary ("USP-NF") standards. Appellant suggests that this difference violates the same-labeling provision in 21 U.S.C. § 355(j)(2)(A)(v), which requires ANDA applicants to "show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug . . . except for changes required . . . because the new drug and the listed drug are produced or distributed by different manufacturers."

The key phrase in the statute is "labeling *approved* for the listed drug." The FDA has concluded that Hill's amino-acid

testing method has not been validated and has thus instructed to Hill to remove this line from its labels. The agency has instead decided that the use of peanut oil refined according to USP-NF standards (basically, heat to 475°F for 15 minutes) is sufficient to reduce peanut proteins to safe levels. Hill's label is not "approved" for the listed drug, so Identi need not copy Hill's statement about a non-validated method. Moreover, 21 C.F.R. § 314.94(a)(8)(iv), the regulation implementing this labeling requirement, specifically states that the different-manufacturers exception "may include . . . labeling revisions made to comply with current FDA labeling guidelines or other guidance."

Hill's briefing makes a number of hyperbolic references to the "immutable laws of science," but the basic tenets of administrative law have greater impact on our decisions. The FDA's actions were not arbitrary and capricious, and the district court's grant of summary judgment is affirmed.

So ordered.