09-1832-cv

In the

United States Court of Appeals

For the Second Circuit

HIFI DNA TECH LLC,
Plaintiff-Appellant,

– v. –
–

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES FOOD & DRUG ADMINISTRATION, KATHLEEN SEBELIUS, O/, SEC. OF U.S. HEALTH AND SVCS., MARGARET HAMBURG, O/, COMM. OF U.S. FOOD & DRUG ADMIN.,
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

REPLY BRIEF FOR PLAINTIFF-APPELLANT

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ARGUMENT

Much of Defendants' Brief recites facts and basic device law with which Plaintiff does not quarrel. But Defendants continue to raise the specter of cancer and claim that Plaintiff's virology test is a cancer test. Because this fundamental mistake colored FDA's entire analysis, FDA's decision cannot stand.

First, Defendants state that "HiFi did not submit any information demonstrating that there existed an HPV genotyping test that had been validated for diagnostic use with respect to cervical cancer." Def.s' Br. at 26. They make this statement even while asserting that "Genotyping can be used to determine which of the many types of HPV that infect humans are present in a particular specimen, and is useful in identifying whether an HPV infection is caused by a particular high-risk HPV type. See JA 25, 34 n.25." Def.s' Br. at 14. These two statements can be reconciled only by the acknowledgment that HPV is a virus and does not necessarily equate with cancer. Only a persistent infection of HPV with a high-risk type of HPV can lead to cancer. See Pl.'s Br. at 10. HPV genotyping shows only what type of HPV exists in a particular clinical sample – it does not show cancer.

Similarly, "FDA determined that, to demonstrate clinical effectiveness, HiFi must provide data on the proportion of women with cervical precancer/cancer who have a positive test with the HPV Device ("clinical sensitivity") and the proportion of women without cervical precancer/cancer who test negative with the HPV Device ("clinical specificity")." Def.s' Br. at 28. Again, the presence or absence of HPV at any particular time does not indicate the presence or absence of cancer, and this determination is therefore illogical. Even FDA's documents make this clear. See JA 24. This argument, and all of Defendants' related argument regarding specificity and sensitivity, therefore fails.

Defendants' argument regarding the disparate treatment FDA has given tests for *H. pylori* both misstates Plaintiff's position and overstates the holding of the Court in Contact Lens Mfrs. Assn. v. FDA, 766 F.2d 592 (D.C. Cir. 1985). Plaintiff raised the disparate treatment issue to show that FDA acted arbitrarily by designating one test for a virus that may lead to cancer as a virus test and another test for a virus that may lead to cancer as a cancer test. Plaintiff made this comparison to show that evaluating its device as a cancer test was contrary to past practice. Similarly, the Court in Contact Lens, far from simply rejecting the claim that disparate treatment existed as asserted by Defendants herein, stated that: "We are troubled,

nonetheless, by the argument that the FDA's treatment of RGP lenses, even if internally logical and supported by several comments in the record, is impeached by the agency's action in other dockets." Id. at 602 (emphasis added). The Court further stated that the issue was not ripe for consideration, but that "should the FDA ultimately decide to treat [different types of contact] lenses differently, we will not feel that our respect for the agency's judgment has been vindicated unless the FDA explains why such a distinction is coherent." Id. at 603. While justifications for disparate treatment may exist, nothing in the record or court papers justifies it in this case. As Contact Lens makes clear, courts should be wary of such unexplained discrepancies.

Defendants also continue to insist that probes and primers have no substantive difference. Conspicuously absent from Defendants' Brief is any definition of either term. Defendants neither explain what they believe each does nor why it makes no difference what term is used. It is difficult to fathom that in science, any less than in law, terms that mean different things can be used interchangeably without consequence or even, as here, definition. As noted in Plaintiff's Brief at page 20, the rest of the world notes a difference. Failure to do so is further indication of FDA's failure to properly evaluate Plaintiff's petition.

Lastly, these issues demonstrate the need for evidence outside the record. FDA gave Plaintiff no opportunity to address these issues at the agency level. If FDA is permitted to simply create its own definitions and ignore its own practices, its decisions, "even if internally logical and supported by several comments in the record," (Contact Lens Mfrs. Assn. v. FDA, 766 F.2d at 602) can be the product of arbitrary and capricious behavior (intentional or not) by FDA officials. Plaintiff's Brief sets forth its argument for evidence outside the record to be allowed in this case.

CONCLUSION

FDA's decision was arbitrary and its defenses continue to be. Plaintiff requests that this Court reverse the trial court and order FDA to grant the petition or, in the alternative, remand the case to the district court for further factfinding.

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CERTIFICATE OF SERVICE

I hereby certify that on the above date a copy of the foregoing was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e mail to all parties by operation of the court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the court's CM/ECF System.

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Anthony J. Musto
October 7, 2009