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Federal Circuit Changes the Game for Selling Single-API Drugs to the Government

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Selling drugs to the Government just got a lot simpler. In *Acetris Health LLC v. United States*, No. 2018-2399 (Feb. 10, 2020), the Federal Circuit opened the Government door to all drugs "manufactured"—that is, measured, weighed, mixed, and compounded—in the United States, regardless of where the active pharmaceutical ingredient ("API") originates. This is a vast departure from the status quo prior, where agencies relied on the U.S. Customs and Border Patrol ("CBP") to determine whether foreign-made API had been substantially transformed so as to be compliant with the Trade Agreements Act of 1979 ("TAA"), and thus saleable to the Government. In *Acetris*, the Department of Veterans Affairs ("VA") relied on a decision by CBP to take the position that processing and pressing API from India into pill form in the United States did not "substantially transform" the API so as to make the resulting drug compliant with the Trade Agreements Act ("TAA"). The Federal Circuit disagreed, holding that "the source of the components (here, the API) is irrelevant in determining where a product is 'manufactured'" for purposes of the Federal Acquisition Regulation's ("FAR") TAA clause. For the time being, the *Acetris* decision thus ostensibly wipes out country of origin concerns for pharmaceutical companies who perform the final processing of their drugs in the United States.

The *Acetris* decision impacts single-API drugs most dramatically. Under prior CBP decisions, single-API drugs, where the API's country of origin was not compliant with the TAA, could almost never be sold to the Government. CBP has applied a substantial transformation test, taking the position that merely pressing a single API into pill form did not alter its medicinal effect or chemical structure, and thus does not satisfy the TAA substantial transformation test. Processing, even where extensive, does not substantially transform a single API into something different unless, for example, it increases the drug's efficacy. Drugs made from multiple APIs were a little easier—CBP has held that combining APIs substantially transforms them.

In *Acetris*, the Federal Circuit has taken the substantial transformation test out of the equation, holding that drugs could instead comply with the TAA through the manufacturing door of the FAR TAA clause. Under *Acetris*, single-API drugs that are mixed and compounded in the United States are "manufactured" in the United States and thus qualify for sale to the Government, regardless of the API's country of origin. The Federal Circuit also removed CBP from the mix, declaring "there is 'not a requirement' for the VA to defer to the CBP's determination." Thus, according to the Federal Circuit, CBP's country of origin determinations are not binding on agencies procuring

pharmaceuticals.

This shift in the legal framework for Government procurement of drugs may also make life easier for pharmaceutical companies in another way. The FDA has long interpreted the place of manufacture for pharmaceutical products as the place in which the drug is last manufactured. The FDA's definition of manufacturing includes such processing as pressing API into pill or tablet form and even filling drugs into bottles. Thus, the place of manufacture for purposes of FDA labeling requirements has sometimes conflicted with the CBP's country of origin designation, particularly for single-API drugs as explained above. But, under *Acetris*, these two definitions may align much more often, reducing the compliance burden on pharmaceutical companies in juggling multiple regulatory standards. This will not be a perfect alignment, however; it is still unclear whether something short of the processing performed by Acetris—measuring, weighing, mixing, and compounding a drug—could satisfy the FAR TAA clause manufacturing standard.

There likely will be a large ripple in the coming months as agencies try to make sense of this significant decision and its implications for their procurements. At the very least, pharmaceutical companies selling to the Government now have fuel for more meaningful contract negotiations, whether in adding drugs with non-TAA country of origin API to their Federal Supply Schedules or settling claims arising from potentially non-compliant drugs.

[1] For a more comprehensive background on the decision and its implications in government contracts generally, please see the blog by my colleagues here.

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