# Healthier Choices Management Corp. v. Philip Morris USA, Inc. No. 22-1268 (Fed. Cir. Apr. 12, 2023)

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This case addresses pleading standards in view of contradicting factual assertions and a complaint's disavowal of statements in an exhibit.

#### **Background**

Healthier Choices Management Corp. ("HCM") sued Philip Morris for patent infringement accusing Philip's "electronic nicotine delivery system" called the IQOS system. HCM's patent claims an electronic smoking device, that includes a limitation that recites a "combustible material reservoir" that "initiat[es] a combustion reaction in the combustible material reservoir."

Philip Morris markets the IQOS system as a "heat-not-burn" system, claiming that the heat does not result in burning of the tobacco. HCM included an exhibit in its original complaint Philip Morris' Modified Risk Tobacco Production Application (MRTPA). Philip Morris argued that the MRTPA showed that the IQOS did not initiate a combustion reaction and thus Philip Morris did not infringe.

The district court agreed with Philip Morris and dismissed the complaint. HCM moved for leave to file an amended complaint, removing its reference to the MRTPA and attached an expert declaration opining that the IQOS system resulted in some burning and therefore the IQOS infringed the patent.

However, the district court determined that the HCM failed to plausibly allege, in either the original or the amended complaint, that the IQOS system initiates a combustion reaction and thus denied HCM's motion for leave to amend the complaint.

#### Issue(s)

Did the district court err by dismissing the original complaint?

Did the district court err by denying HCM's motion for leave to amend the complaint?

### Holding(s)

The district court erred on both issues.

## Reasoning

Regional circuit law applies when reviewing motions to dismiss for failure to state a claim under Rule 12(b)(6). Under the Eleventh Circuit law, a district court can consider exhibits attached to a complaint in ruling on a motion to dismiss and if the allegation of the complaint about a particular exhibit conflicts with the contents of the exhibit itself, the exhibit controls. But this does not mean that factual assertions made in an exhibit always control over contrary factual assertions on the same subject made in a complaint. Similarly, when a complaint contains specific, well-pleaded allegations that either do not appear in the attached exhibit or that contradict conclusory statements in the exhibit, courts in the Eleventh Circuit credit the allegations in the complaint.

In its original complaint, HCM disagreed with Philip Morris' MRTPA and specifically referred to defendant's test result that specified "97%, not 100%, of the harmful chemicals associated with combustion are eliminated by the Accused Infringing Product," and combustion markers were still present. This allegation explained why HCM disagreed with Philip Morris's characterization in the MRTPA of the IQOS system as combustion-less. The Federal Circuit found that these allegations were neither general nor conclusory since they were supported by defendant's own tests. The allegation successfully asserted a plausible theory for why the IQOS system might nonetheless initiate combustion despite Philip Morris' contrary marketing. The Federal Circuit reasoned that when construing the complaint in a light most favorable to the plaintiff and accepting as true all facts the plaintiff alleges, the allegations were sufficient to disavow the contradictory statements in the MRTPA.

In the Eleventh Circuit, district courts may consider a document outside the pleading and treat it as part of the pleading for purposes of Rule 12(b)(6) if the document is "(1) central to the plaintiff's complaint; and (2) undisputed." HCM did not attach the MRTPA in its amended complaint and removed any citations to the MRTPA, but continued to allege that combustion occurs in the IQOS system. HCM included an expert declaration that contained testimony that concluded combustion.

The Eleventh Circuit "do[es] not permit a district court to consider, on a motion to dismiss, exhibits attached to an earlier complaint that a plaintiff has expressly disavowed or rejected as untrue in a subsequent amended complaint." There is no requirement of magic words to disavow statements made in an exhibit. HCM disavowed the statements contained in the MRTPA in its original complaint and its exclusion from the amended complaint also satisfies the disavowal.

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