



## **Initial Determination Finds ACON's 3-1 Lipid Panels Infringe PTS Diagnostics' Patents**

*United States International Trade Commission issues initial determination finding ACON's 3-1 Lipid Panels infringe PTS Diagnostics' Patent Nos. 7,087,397 and 7,625,721*

INDIANAPOLIS (June 6, 2019) – PTS Diagnostics announced today that an administrative law judge of the U.S. International Trade Commission (ITC) issued a notice of initial determination on June 4, 2019, in Investigation No. 337-TA-1116 finding ACON Laboratories, Inc. and ACON Biotech (Hangzhou) Co.'s (ACON) 3-1 Lipid Panels have violated Section 337 of the Tariff Act by importing devices that infringe PTS Diagnostics' U.S. Patent Nos. 7,087,397 and 7,625,721. The ruling is an important step toward PTS Diagnostics obtaining an order excluding ACON's 3-1 Lipid Panels from importation into the United States.

The ITC is a U.S. federal agency charged by Congress to investigate unfair trade practices that impact U.S. domestic industries. In the initial determination, the ALJ found that ACON's 3-1 Lipid Panels infringe claims of both the '397 patent and the '721 patent. Further, the ALJ found that all of PTS Diagnostics' patents asserted in the investigation are valid, rejecting all of ACON's arguments to the contrary. The ALJ concluded that ACON's importation into the U.S., sale for importation, or sale in the U.S. following the importation of the ACON 3-1 Lipid Panels violated section 337 of the Tariff Act.

The PTS Diagnostics patents asserted in the investigation cover PTS Diagnostics' CardioChek® family of lipid analyzers and PTS Panel test strips, which are made in the U.S. PTS Diagnostics is pleased that the initial determination found that ACON 3-1 Lipid Panels infringe these patents, and the company will pursue an order from the ITC excluding all ACON infringing products from the U.S. PTS Diagnostics was represented in the ITC proceeding by Haynes and Boone, LLP.

"PTS Diagnostics appreciates the administrative law judge's thorough consideration after extensive briefing and a hearing and the determination that ACON has infringed our patents," said Robert Huffstodt, President and CEO of PTS Diagnostics. "PTS Diagnostics is proud that the healthcare industry has widely embraced our CardioChek lipid measurement system, which has been used to screen more than 140 million patients worldwide. Further, this investigation demonstrates that we are committed to protecting ourselves against anyone who infringes our broad worldwide patent portfolio."

Recognizing the strong connection between heart attack, stroke, and diabetes, CardioChek analyzers provide rapid point-of-care blood-chemistry values and measurements to help identify at-risk individuals. As one of the fastest, most cost-efficient and user-friendly analyzers on the market today, CardioChek systems accurately test lipid profile and glucose simultaneously with

one fingerstick. In as little as 90 seconds, they provide on-site results with similar accuracy to clinical laboratories.

PTS Diagnostics' PTS Panels® lipid test strips measure total cholesterol, HDL cholesterol, and triglycerides, calculate LDL cholesterol and TC/HDL ratio, and do not require refrigeration. The accompanying meter is handheld, battery-operated, and compact and lightweight, making it easy to transport and store. CardioChek systems are CLIA-waived and meet NCEP guidelines for accuracy and precision. The CardioChek Plus analyzer offers simultaneous testing of lipid profile and glucose, has wireless communication capabilities, and is CRMLN-certified for total cholesterol and HDL cholesterol testing.

PTS Diagnostics will fully defend the ITC's initial determination against any efforts for review or appeals.

### **About PTS Diagnostics**

*Through its People, Technology and Service, PTS Diagnostics creates health innovation that drives action and results. Since 1992, we have helped medical professionals and patients achieve better health outcomes through our accurate, precise, fast, affordable, and certified point-of-care medical devices. Healthcare professionals have used our CardioChek® products to assess cardiovascular disease risks for more than 140 million patients worldwide through lipid panel screening. And, our AICNow® systems, which provide fast and reliable HbA1c testing, have helped physicians deliver more effective treatments to patients with diabetes. From our headquarters in the United States of America, we design, manufacture, and market our products to more than 130 countries around the globe. For more information, visit [ptsdiagnostics.com](http://ptsdiagnostics.com).*

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