

## J&J Surgical Rip-Offs Lead To Seizure, FDA Criminal Probe

By Dani Kass

*Law360 (June 24, 2020, 10:18 PM EDT)* -- An Illinois federal judge has ordered law enforcement to seize counterfeit versions of Johnson & Johnson surgical devices from a distributor that's repeatedly covered up its involvement in international fraud, according to documents unsealed Wednesday.

U.S. District Judge Robert M. Dow Jr. didn't mince words when granting Johnson & Johnson unit Ethicon's request to raid three locations for the company operating as eSutures.com and seize business records and counterfeit products.



Geoffrey Potter

"Upon the evidence presented, it is highly likely that by knowingly selling and helping manufacture counterfeit Ethicon surgical devices, eSutures engaged in criminal counterfeiting," Judge Dow said. "The incentives for eSutures to cover up its criminal behavior are clear, as is its history of flouting federal discovery and attempting to conceal or destroy evidence. eSutures is precisely the type of defendant that Congress had in mind when it authorized ex parte seizure orders in the Counterfeiting Act."

The June 16 seizure order is in Ethicon's trademark case, which overlaps with a U.S. Food and Drug Administration's Office of Criminal Investigation probe into the Illinois company. Judge Dow has also granted Ethicon a temporary restraining order, barring eSutures from using any of the J&J unit's marks, among other activity.

Ethicon's June 15 suit accuses Advanced Inventory Management Inc., which operates as eSutures.com, its top officials and two employees of importing and selling dangerous counterfeit versions of Ethicon's Surgicel, LigaClip and SecureStrap products.

"Testing shows that the counterfeit versions of these devices are bacterially contaminated and critically defective," the complaint states. "The counterfeits being trafficked by eSutures pose a serious risk to the health and lives of unsuspecting patients."

According to court records, eSutures got its products from an Indian company called M/S Medserve and its owner Pritamdas Arora, which have faced their own reckoning for the counterfeiting. Between litigation in India and Florida, Ethicon was able to search Medserve's offices and Arora's home, which led

to "incontrovertible evidence" of counterfeiting, the complaint states.

For example, during that seizure, Judge Dow said Medserve received a package from China that featured thousands of counterfeit LigaClips products, "delivered in full view of Ethicon's counsel and Indian law enforcement."

During the Florida proceedings, Ethicon subpoenaed eSutures, which was not a named party. Judge Dow said eSutures withheld documents and provided a response "calculated to conceal all evidence of its counterfeiting while portraying that it was merely a legitimate supplier." After that "fraudulent" response, he said the company unsuccessfully attempted to sell off its supply to Medserve distributors in Dubai.

eSutures had also been in talks with a gray-market distributor over the WhatsApp messaging service, and when that distributor was named in the Florida litigation, an eSutures employee said "delete my texts and my number ... from ur cell," the judge said.

That reliance on WhatsApp was part of why Judge Dow granted the seizure.

"It takes only seconds for a user to delete WhatsApp messages from his or her phone," the order states. "Providing eSutures notice of this lawsuit before an ex parte seizure would allow them to immediately and irretrievably delete their incriminating WhatsApp messages."

Ethicon said eSutures was well aware of what it was doing, as Medserve had admitted that its products were counterfeit and that its business was illegal.

The complaint notes that eSutures did sell genuine Ethicon products at times, but that it obtained them in fraudulent ways. Ethicon said eSutures would pay surgery center employees to divert properly purchased and highly discounted products for eSutures to then resell.

Judge Dow's order said the FDA's Office of Criminal Investigations is investigating the counterfeiting, with Ethicon's cooperation. The agency told Ethicon that eSutures bought SecureStrap devices from a gray market distributor in Turkey, and then sold them in the U.S., the order states.

The judge also noted that in April 2019, eSutures stopped getting the counterfeits delivered to its warehouse, and instead sent them to employee homes — which will also be searched under the seizure order.

"For these deliveries, eSutures instructed Medserve to scrub its invoices of all references to eSutures, including removing the employees' company email addresses," the order states. "The obvious explanation, and the only plausible one, is that eSutures knew it was purchasing counterfeits and was actively attempting to avoid detection by Ethicon and the government."

The complaint asks for a permanent injunction and punitive damages of at least \$25 million, among other financial relief.

"At Ethicon, public health and patient safety is our primary concern," the company said in a statement to Law360. "Recently, we became aware of the existence of counterfeit Ethicon products. We alerted the appropriate authorities to address the issue and protect patient safety. To guarantee quality and authenticity, we encourage hospitals and healthcare providers to buy Ethicon's products only from

authorized distributors or sales representatives."

Counsel for eSutures didn't immediately respond to a request for comment Wednesday evening.

Ethicon is represented by Bradley J. Androozzi and Matthew M. Morrissey of Faegre Drinker Biddle & Reath LLP and Geoffrey Potter, Aron Fischer, Timothy A. Waters and Joshua R. Stein of Patterson Belknap Webb & Tyler LLP.

ESutures and the individual defendants are represented by Alexander S. Vesselinovitch and Matthew T. Connelly of Freeborn & Peters LLP and Michael S. Denniston, Gregory G. Marshall and Jack W. Selden of Bradley Arant Boult Cummings LLP.

The case is Johnson & Johnson et al. v. Advanced Inventory Management Inc. et al., case number 1:20-cv-03471, in the U.S. District Court for the Northern District of Illinois.

--Editing by Michael Watanabe.