

**FOR IMMEDIATE RELEASE**

**Federal Appeals Court Ruling Affirms Amneal's Green Light to Market  
New Esomeprazole Strontium Delayed-Release Capsules**

***Decision eliminates risk of patent infringement by Amneal and partner Hanmi***

Bridgewater, NJ (USA), December 23, 2013 – Amneal Pharmaceuticals LLC today applauded the December 19 decision by the U.S. Court of Appeals for the Federal Circuit (CAFC) in favor of South Korea-based Hanmi Pharmaceutical Co. Ltd. that AstraZeneca PLC's patents do not cover Hanmi's Esomeprazole strontium delayed-release capsules.

The CAFC quickly affirmed the decision of the lower district court, effectively removing all legal risk of Hanmi and Amneal being subject to patent infringement damages by AstraZeneca. The judgment removes a major hurdle for Amneal, which is marketing the product in the U.S. under an exclusive license and distribution agreement with Hanmi. Amneal launched branded Esomeprazole strontium delayed-release capsules 49.3 mg, a 505(b)(2) NDA drug, on December 17.

The CAFC summarized its findings as follows: "The written description of the '504 patent contains a clear disclaimer of claim scope, and no other aspect of the intrinsic record clearly points the other way. We therefore conclude that the district court's construction of 'alkaline salt' was correct, and we affirm the judgment of noninfringement based on that construction." Full text of the CAFC opinion can be accessed at <http://www.cafc.uscourts.gov/images/stories/opinions-orders/13-1490.Opinion.12-17-2013.1.PDF>.

"The appellate court adopted the position that Hanmi and Amneal advocated from the outset – specifically, that the Hanmi esomeprazole strontium capsule product does not infringe the patents asserted by AstraZeneca. Moreover, Amneal's recent launch will proceed free from the legal uncertainty that may have been perceived before last week's favorable decision," said Kenneth M. Cappel, Amneal's Vice-President of Global Intellectual Property.

*About Amneal Pharmaceuticals LLC*

Amneal Pharmaceuticals LLC is a U.S.-based manufacturer of generic pharmaceuticals. Known as "Generic's New Generation", Amneal prides itself on its unwavering commitment to quality, meaningful business relationships, and innovative approach to maximizing value for all stakeholders. Extensive investment in R&D, an intelligently aggressive expansion strategy, and focus on vertical integration are key contributors to the company's impressive growth over the past several years. Amneal is headquartered in Bridgewater, New Jersey with manufacturing, R&D, packaging, sales and distribution facilities throughout the U.S., as well as abroad. For more information, visit [www.amneal.com](http://www.amneal.com).

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CONTACTS:

Jim Luce  
Executive Vice President, Sales & Marketing  
Amneal Pharmaceuticals, LLC  
Direct: 949-610-8018  
Email: [jim@amneal.com](mailto:jim@amneal.com)  
[www.amneal.com](http://www.amneal.com)  
620 Newport Center Drive, 14th Floor  
Newport Beach, California 92660

Cheryl Lechok  
President  
Cheryl Lechok Communications, LLC  
PH: 203-961-9280  
M: 203-613-1506  
Email: [clechok@optonline.net](mailto:clechok@optonline.net)  
[www.linkedin.com/in/clechok](http://www.linkedin.com/in/clechok)  
30 Glen Terrace  
Stamford, CT 06906