

## Venus Remedies' patent on salbactam with ceftriaxone opposed in Delhi patent office

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A drugs control officer in Rajasthan, Manoj Tongra has opposed a product patent recently granted by the Delhi patent office to Chandigarh-based pharmaceutical company, Venus Remedies, for salbactam with ceftriaxone with EDTA (patent no 236996, dated December 4, 2009). The product, which is manufactured by several companies under different brand names, is indicated for infections.

Tongra, a patent expert in the country who has done his patent course at WIPO, Geneva, in his patent opposition filed at Delhi patent office said that he is opposing the patent on the grounds that it lacks innovation, lacks inventive step and things which are not patentable under section 3 (d) (e) of Patent Act. There is a major legal battle going on in the country between Novartis, Natco and other public interests groups regarding this section of the Act.

"I want to oppose this patent on grounds under section 25(2) read with section 2(1)(j), 2(1)(ja), 2(1)(l) and section 3(d), (e) of the patent act. First is lack of invention section 2(1)(j), lack of inventive step section. Second is invention not patentable chapter II, section 3 (d) and 3(e)," Tongra said in his patent opposition.

"We consider first claim and they lack as per section 2(1) (ja), and lack of new invention section 2(1)(l) all the claim made are based first on combination of ceftriaxone with sulbactam and then addition of EDTA to improve the quality of product and particulate matter but combination is disclosed in prior art is not disclosed in patent background of invention patent claim as follows (a) ceftriaxone sodium, present in an amount of 2g, calculated as ceftriaxone free acid, (b) sulbactam sodium, present in an amount of 1 g, calculated as sulbactam free acid and, (c) EDTA or a pharmaceutically acceptable salt thereof present in an amount of about 2 mg, said composition being reconstituted with about 20 ml of aqueous solvent, wherein total amount of sodium content of said ceftriaxone sodium and sulbactam sodium is about 264.6 mg with 11.48 mEq of sodium," Tongra argued.