The positive role of intellectual property in the creation of cost effective and affordable biosimilars

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Intellectual property particularly patents are considered to be roadblocks in the development and prolific use of Biosimilars. The drug and pharmaceuticals business tends to equate Biosimilars with synthetic generics. However, this comparison is unwarranted since cell lines developed independently can never be identical. Biosimilars can never be copied. They can only be developed independently. Also it takes infinitely more effort and expense to develop Biosimilars. Patents are territorial in nature. Each country has its own rules for covering active drug substances made by or derived from a living organism for example by use of recombinant DNA or uncontrolled gene expression. Also biologic medical products covered in one country may not be covered in others. Therefore there is a vast storehouse of technology reported in patent documents in one country that is waiting to be worked in another country where a patent application was not filed. Biosimilars researches and manufactures should make it a point to use the database of patents available to them as the basic research source to build new cell lines and create their own molecular clones and cell banks. These documents provide details of new fermentation and purification processes to create Biosimilars with reduced side effects and less threatening immunogenic responses. Patent documents also provide new techniques for assays and pharmacovigilance plans.

Biography
Mohan Dewan is the Principal of R.K. Dewan & Co., with over 40 years of experience in the field of Intellectual Property Rights. He is a practicing Advocate and Jurist and also a registered Patent & Trademark attorney. He has the unique distinction of being an exceptional litigator along with being an expert in Patent & Trademark prosecution. Having drafted and successfully prosecuted several thousand patent specifications, he has come to be acknowledged as a specialist in patent specification drafting. He has obtained over 5000 patents for various Indian and foreign clients in almost every sphere of technology. His firm represents over 4000 clients worldwide.

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