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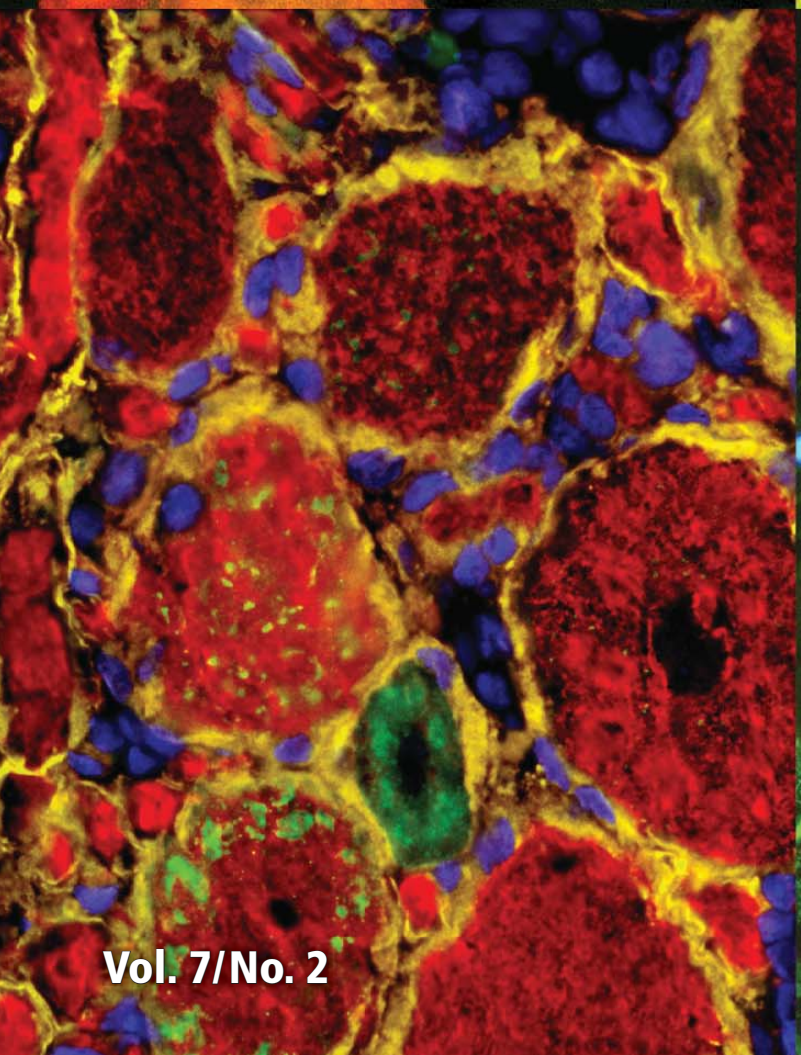

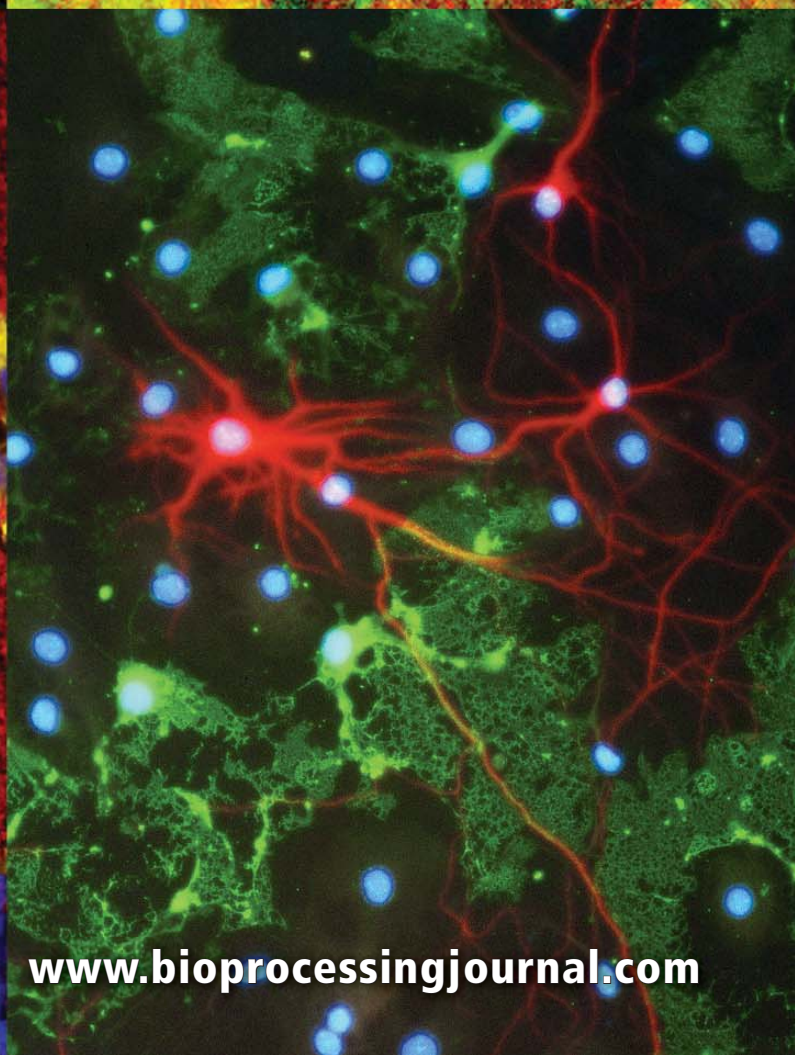

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from the publisher

I may be missing something, but I just don't understand why there is so much interest in what are called "biosimilar" products. As you know, this term is used to describe a biological product that is so similar to a licensed product that they would be indistinguishable. And since this concept has worked so well for generic pharmaceuticals, the operative term for these products was originally "biogeneric."

But is this a practical concept? Can biologics be compared to pharmaceutical products which result from well-defined chemical formulations and raw materials? And if they can be compared, which comparisons are valid and with what degree of confidence?

There are many examples of efforts to make biosimilar products, such as every time a product is taken to a larger scale, and when an established product is transferred to another facility, including a contract manufacturing site. While most of these examples have resulted in products which were indistinguishable for all practical purposes, others revealed troubling differences during product characterization or clinical administration.

Then there are the countless process changes such as bioreactor type, nutrients, feed strategy, filtration material, chromatography media, pump type, and tubing material. Certainly any of these changes, or a change in the company that supplies a critical material, have been shown to result in a product with subtle, if not substantial differences. Even a change in final product formulation or container closer has caused serious immunogenicity problems for a product that had been on the market for many years.

Now let's consider a company that wants to make a biosimilar product. Unless this company can license or steal the cell line from the original product manufacturer, it will be working with a different cell line — even when using the same plasmid. Then the company would have to reverse-engineer the process for the licensed product, or obtain the process via license or industrial espionage. But even if these critical aspects can be duplicated, it is almost impossible for the company to obtain the same raw materials, even if they are derived from the same vendors.

Since there would be a different process, cell line, facility, and raw materials — how similar can this product be to the licensed material? The only way to find out is by conducting clinical trials, and if the regulatory agency sees any problems in the data, these trials could be lengthy and very expensive. In the end, I have to question if this approach makes much sense, and to make matters worse, the original product manufacturer could come out with the next-generation product.

My opinion is that characterization data will not be sufficient to show a biosimilar product is similar enough to justify a shortened clinical evaluation, and the product development costs will not justify a "me too" product which the original innovator may soon replace with a better product. There are better business models to follow.

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