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# Product-by-process claims in Brazil: how to obtain effective claims?

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Brazilian courts and the patent office (BRPTO) are evolving in the evaluation of process claims. Key decisions on both forums are showing how effective those claims can be to protect products in the country.

BRPTO's Rule #124/2013 (items 3.60 and 3.61) and Rule #169/2016 (item 4.17) set forth that product-by-process claims are allowable as long as the product ***(i)*** fulfills the patentability requirements (*i.e.*, it is novel and non-obvious regardless of the obtaining process) and ***(ii)*** cannot be described otherwise. Meeting these requirements can be a challenge.

As for novelty, a person skilled in the art must conclude that the process results in a product with a structure and/or composition different from that of the product disclosed in the state of the art. Additionally, a non-obviousness feature must be evidenced. It is this feature that generally allows to conclude that the product contains a distinct characteristic from the state of the art (*e.g.*, a different internal structure).

Rule #124/2013 exemplifies a material whose preparation process includes a new sintering step. The resulting product has greater mechanical resistance compared to the materials of the state of the art that share the same composition, but it is not possible to describe the material *per se*. In this case, the claim is novel. Rule #169/2016 provides another acceptable example: a glass cup produced by a process X comprising a heat treatment step at a certain temperature not described in the prior art, in which the glass cup has a greater breaking strength compared to the state of the art. This indicates that the claimed glass has a different microstructure due to the different manufacturing process.

A successful and rare case related to product-by-process claims in the biotech field is the PI0815946-7 patent, which claims read as follows:

1. *An article of manufacture, **characterized** by comprising a packaging material which comprises a label for use in treating ischemia, said packaging material packaging a pharmaceutically effective amount of adherent placental cells, wherein at least 10 % of said adherent cells are at a proliferative phase, wherein said cells are propagated using a three-dimensional (3D) culture, and wherein culturing conditions of said three-dimensional culture comprise an adherent material which is polystyrene.*

2. *The article of manufacture according to claim 1, **characterized** in that said three-dimensional (3D) culture is effected in a 3D bioreactor.*
3. *The article of manufacture according to claim 1 or 2, **characterized** in that culturing of said cells in said 3D culture is effected under perfusion.*
4. *The article of manufacture according to claim 3, **characterized** in that said perfusion rate is adjusted in order to maintain a constant glucose concentration in the culture medium.*
5. *The article of manufacture according to claim 4, **characterized** in that said constant glucose concentration is 550 ± 50 mg/liter.*

*(…)*

During the examination procedure, in order to overcome the BRPTO's objections related to the characterization of the product by its obtaining process, the patentee demonstrated that: ***(i)*** it was impossible to define the claimed product in any other means, as the cells could not be clearly distinguished from 2D-expanded cells by their structural characteristics, given the overlap of marker expression between the two populations; and ***(ii)*** the way in which the cells were produced provided particular therapeutic characteristics to the invention. The BRPTO accepted said arguments and granted the patent.

Another example is the PI0317064-0 patent, which independent product-by-process claim is reproduced below.

1. *A composition for producing an antitumor immune response, characterized in that it comprises $10^2$ to $10^{10}$ of a cell population comprising dendritic cells that have been partially matured* in vitro*and 10% dimethyl sulfoxide (DMSO), wherein the partially matured dendritic cells demonstrate a cell surface phenotype consisting of an up-regulated expression of CD80, CD86 and/or CD54 when compared to immature dendritic cells, a cytokine profile demonstrating the production of TNF-?, IL-6, IL-10 and/or IL-12 and wherein the partially matured dendritic cell can take up and process antigen,*

*wherein the induction of maturation process is carried out with the inactivated Bacillus Calmette-Guerin (BCG) and interferon-gamma (IFN?) maturation agents and is carried out over a time period of 4, 8 or 24 hours.*

*(…)*

The BRPTO's Boards of Appeal concluded that "*Product claims defined in terms of process are exception wording for cases wherein the product cannot be described otherwise (see item 3.60 of Rule #124/2013). This appears to be the case with the present application. If the process is excluded from the claim, the definition by phenotypic characteristics alone will remain imprecise. That said, it is understood that the process, including the agents and the time of exposure to the agents are essential characteristics of the cells that need to be included in the wording of the claims*".

It is worth mentioning that, in cases wherein the BRPTO does not accept a product-by-process claim, Rule #93/2013 provides another exception that may allow the applicant to seek protection for the process. Although changes to the claim category are generally not accepted during substantive examination, a claim that originally defined a product by its obtaining process can be redrafted to define the process. In other words, a product-by-process claim can be redrafted to a

direct process claim.

Considering all the above, for applicants seeking to obtain product-by-process claims in Brazil, it may be necessary to submit additional evidence during examination, including experiments and affidavit(s), attesting that the process results in a product with a structure and/or composition different from the state of the art and which exhibits non-obviousness, in addition to show that it is not possible to define the product by any other means.

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