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Further Development of Artificial Pancreas: Blocked by Patents?

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Abstract

Patent activity in the field of medical device technology and especially in the area of artificial pancreas development has surged in recent years. According to the search presented in this article, the number of granted U.S. patents in the area of closed-loop glucose control (CLGC) increased from 24 filed in 1991 to 247 filed in 2001. A company active in the area of diabetes technology development will likely need to understand a patent landscape consisting of hundreds of patents. Currently, both in the United States and in Europe, patentability requirements seem to be raised in order to ensure patent quality. However, the current patent landscape reflects the work of the patent offices in the past, as already granted patents are not affected by changes made to the patent grant procedure today.

Regarding the increasing amount of patents and considering the complexity of CLGC systems, the attempt to develop a CLGC system will become more and more venturesome regarding the risk of infringement of already existing patents. The consequence of this situation can be that less innovation takes place.

This article highlights some important general aspects of the patent system, briefly characterizes the current CLGC patent landscape, and illustrates by means of two exemplary patents what one angle of said patent landscape looks like. It is our opinion that, in order to support the rapid development of an artificial pancreas for patients with diabetes, adequate action to lower this hurdle should be undertaken by a consortium of all parties involved (industries, patient organizations, health-care professionals, and institutional payers).

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Abbreviations: (CLGC) closed-loop glucose control, (EPO) European Patent Office, (IPC) international patent classification, (MPC) model predictive controller, (PID) proportional integral derivative, (USPTO) United States Patent and Trademark Office

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