35 USC 103(b) and Biotechnology Process Inventions

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United States law contains special requirements for patent applications disclosing nucleotides or amino acid sequences. 35 USC 103(b) has special provisions relating to biotechnology process inventions that affect when to present claims to biotechnology processes. This paper reviews those statutory and regulatory requirements.

35 USC 103(b) states that:

> (1) Notwithstanding subsection (a) [subsection (a) means 35 USC 103(a), which provides the general test for obviousness under U.S. law], and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if (A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and (B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.
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> (2) A patent issued on a process under paragraph (1)(A) shall also contain the claims to the composition of matter used in or made by that process, or (B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.
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> (3) For purposes of paragraph (1), the term “biotechnological process” means (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to (I) express an exogenous nucleotide sequence, (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or (iii) express a specific physiological characteristic not naturally associated with said organism; (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

Section (b)(1) states that, if the applicant makes a "timely election by the applicant for patent to proceed under this subsection" then a "biotechnological process using or resulting in a composition of matter" will *de jure* be deemed non-obvious if claims to the "composition of matter" in an application having the same effective filing date are deemed non-obvious. In other words, if the applicant makes a timely election under section (b)(1) then the world of possible patent defeating prior art is narrowed for the biotechnology process claims. This is desirable for any applicant.

37 CFR contains no specific rule specifying procedure for making a 35 USC 103(b) "timely election." However, MPEP 706.02(n) provides the following guidance:

> An election to proceed under 35 U.S.C. 103(b) shall be made by way of

> petition under 37 CFR 1.182. The petition must establish that all the requirements set forth in 35 U.S.C. 103(b) have been satisfied.
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> An election will normally be considered timely if it is made no later than the earlier of either the payment of the issue fee or the filing of an appeal brief in an application which contains a composition of matter claim which has not been rejected under 35 U.S.C. 102 or 103.
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> In an application where at least one composition of matter claim has not been rejected under 35 U.S.C. 102 or 103, a 35 U.S.C. 103(b) election may be made by submitting the petition and an amendment requesting entry of process claims which correspond to the composition of matter claim.

This guidance suggests that an election presented after appeal (to treat biotechnology process claims under 35 USC 103(b)) would not be timely, and, therefore, such claims could be subject to rejection as obvious even if the biotechnology process uses or results from using a composition of matter that is deemed novel under 102 and non-obvious under 103. Moreover, claims to a process first presented after examination may be withdrawn from examination as constructively non elected.

Accordingly, it would be most effective to present claims to biotechnology processes when the application is filed, and electing to proceed under 35 USC 103(b) as to those claims by filing a suitable petition prior to examination. However, if biotechnology process claims are presented after examination commences, one should elect promptly, in order to proceed under 35 USC 103(b).

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