



General Assembly

January Session, 2021

Raised Bill No. 269

LCO No. 1029



Referred to Committee on GENERAL LAW

Introduced by:
(GL)

AN ACT CONCERNING THE AVAILABILITY OF GENERIC PHARMACEUTICALS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2021*) For purposes of this
2 section and section 2 of this act:

3 (1) "ANDA" means abbreviated new drug application.

4 (2) "ANDA filer" means a party that owns or controls an ANDA filed
5 with the Food and Drug Administration or has the exclusive rights
6 under that ANDA to distribute the ANDA product.

7 (3) "Agreement resolving or settling a patent infringement claim"
8 includes any agreement that is entered into not later than thirty days
9 after the resolution or the settlement of the claim, or any other
10 agreement that is contingent upon, provides a contingent condition for,
11 or is otherwise related to the resolution or settlement of the claim.
12 "Agreement resolving or settling a patent infringement claim" includes,
13 but is not limited to, the following:

14 (A) Any agreement required to be provided to the Federal Trade
15 Commission or the Antitrust Division of the United States Department
16 of Justice under the Medicare Prescription Drug, Improvement, and
17 Modernization Act of 2003.

18 (B) Any agreement between a biosimilar or interchangeable
19 biological product applicant and a reference drug product sponsor that
20 resolves patent claims between the applicant and sponsor.

21 (4) "Biosimilar biological product application filer" means a party that
22 owns or controls a biosimilar biological product application filed with
23 the Food and Drug Administration under subsection (k) of section 351
24 of the Public Health Service Act, 42 USC 262, for licensure of a biological
25 product as biosimilar to, or interchangeable with, a reference drug
26 product or that has the exclusive rights under the application to
27 distribute the biosimilar biological product.

28 (5) "NDA" means new drug application.

29 (6) "Nonreference drug filer" means (A) an ANDA filer, or (B) a
30 biosimilar biological product application filer.

31 (7) "Nonreference drug product" means the product to be
32 manufactured under an ANDA that is the subject of the patent
33 infringement claim, a biosimilar biological product that is the product
34 to be manufactured under the biosimilar biological product application
35 that is the subject of the patent infringement claim, or both.

36 (8) "Patent infringement" means infringement of any patent or of any
37 filed patent application, extension, reissue, renewal, division,
38 continuation, continuation in part, reexamination, patent term
39 restoration, patents of addition and extensions thereof.

40 (9) "Patent infringement claim" means any allegation made to a
41 nonreference drug filer, whether or not included in a complaint filed
42 with a court of law, that its nonreference drug product or application
43 infringes any patent held by, or exclusively licensed to, the reference

44 drug holder.

45 (10) "Reference drug holder" means:

46 (A) A brand holder that is any of the following:

47 (i) The holder of an approved NDA for a drug product application
48 filed under subsection (b) of section 505 of the Federal Food, Drug, and
49 Cosmetic Act, 21 USC 355,

50 (ii) A person owning or controlling enforcement of the patent listed
51 in the Approved Drug Products With Therapeutic Equivalence
52 Evaluations, commonly known as the "FDA Orange Book" in connection
53 with the NDA, or

54 (iii) The predecessors, subsidiaries, divisions, groups and affiliates
55 controlled by, controlling or under common control with, any of the
56 entities described in this subparagraph or subparagraph (B) of this
57 subdivision, with control to be presumed by direct or indirect share
58 ownership of fifty per cent or greater, as well as the licensees, licensors,
59 successors and assigns of each of those entities, or

60 (B) A biological product license holder, which includes any of the
61 following:

62 (i) The holder of an approved biological product license application
63 for a biological drug product under subsection (a) of section 351 of the
64 Public Health Service Act, 42 USC 262,

65 (ii) A person owning or controlling enforcement of any patents that
66 claim the biological product that is the subject of the approved biological
67 patent license application, or

68 (iii) The predecessors, subsidiaries, divisions, groups and affiliates
69 controlled by, controlling or under common control with, any of the
70 entities described in this subparagraph or subparagraph (A) of this
71 subdivision, with control to be presumed by direct or indirect share

72 ownership of fifty per cent or greater, as well as the licensees, licensors,
73 successors and assigns of each of those entities.

74 (11) "Reference drug product" means the product to be manufactured
75 by the reference drug holder and includes branded drugs of the NDA
76 holder and the biological drug product of the biological product license
77 applicant.

78 (12) "Statutory exclusivity" means those prohibitions on the approval
79 of drug applications under subsection (c) of section 505, section 527 or
80 505A of the Federal Food, Drug, and Cosmetic Act, 21 USC 355, 360cc
81 and 355a, or on the licensing of biological product applications under
82 subsection (k) or (m) of section 262 of the Public Health Service Act, 42
83 USC 262.

84 Sec. 2. (NEW) (*Effective October 1, 2021*) (a) (1) Except as provided in
85 subdivision (3) of this subsection, an agreement resolving or settling, on
86 a final or interim basis, a patent infringement claim, shall be presumed
87 to have anticompetitive effects and shall be a violation of this section if
88 both of the following apply:

89 (A) A nonreference drug filer receives anything of value from another
90 company asserting patent infringement, including, but not limited to,
91 an exclusive license or a promise that the brand company will not
92 launch an authorized generic version of its brand drug; and

93 (B) The nonreference drug filer agrees to limit or forego research,
94 development, manufacturing, marketing or sales of the nonreference
95 drug filer's product for any period of time.

96 (2) As used in subparagraph (A) of subdivision (1) of this subsection,
97 "anything of value" does not include a settlement of a patent
98 infringement claim in which the consideration granted by the brand or
99 reference drug filer to the nonreference drug filer as part of the
100 resolution or settlement consists of one or more of the following:

101 (A) The right to market the competing product in the United States

102 before the expiration of either:

103 (i) A patent that is the basis for the patent infringement claim, or

104 (ii) A patent right or other statutory exclusivity that would prevent
105 the marketing of the drug,

106 (B) A covenant not to sue on a claim that the nonreference drug
107 product infringes a United States patent;

108 (C) Compensation for saved reasonable future litigation expenses of
109 the reference drug holder but only if both of the following are true:

110 (i) The total compensation for saved litigation expenses is reflected in
111 budgets that the reference drug holder documented and adopted at least
112 six months before the settlement, and

113 (ii) The compensation does not exceed the lower of the following:

114 (I) Seven million five hundred thousand dollars, or

115 (II) Five per cent of the revenue that the nonreference drug holder
116 projected or forecasted it would receive in the first three years of sales
117 of its version of the reference drug documented at least twelve months
118 before the settlement. If no projections or forecasts are available, the
119 compensation does not exceed two hundred fifty thousand dollars;

120 (D) An agreement resolving or settling a patent infringement claim
121 that permits a nonreference drug filer to begin selling, offering for sale
122 or distributing the nonreference drug product if the reference drug
123 holder seeks approval to launch, obtains approval to launch or launches
124 a different dosage, strength or form of the reference drug having the
125 same active ingredient before the date set by the agreement for entry of
126 the nonreference drug filer. A different form of the reference drug does
127 not include an authorized generic version of the reference drug;

128 (E) An agreement by the reference drug holder not to interfere with
129 the nonreference drug filer's ability to secure and maintain regulatory

130 approval to market the nonreference drug product or an agreement to
131 facilitate the nonreference drug filer's ability to secure and maintain
132 regulatory approval to market the nonreference drug product; or

133 (F) An agreement resolving a patent infringement claim in which the
134 reference drug holder forgives the potential damages accrued by a
135 nonreference drug holder for an at-risk launch of the nonreference drug
136 product that is the subject of that claim.

137 (3) Parties to an agreement are not in violation of subdivision (1) of
138 this subsection if they can demonstrate by a preponderance of the
139 evidence that either of the following are met:

140 (A) The value received by the nonreference drug filer described in
141 subparagraph (A) of subdivision (1) of this subsection is a fair and
142 reasonable compensation solely for other goods or services that the
143 nonreference drug filer has promised to provide, or

144 (B) The agreement has directly generated procompetitive benefits
145 and the procompetitive benefits of the agreement outweigh the
146 anticompetitive effects of the agreement.

147 (b) In determining whether the parties to the agreement have met
148 their burden under subdivision (3) of subsection (a) of this section, the
149 factfinder shall not presume any of the following:

150 (1) That entry into the marketplace could not have occurred until the
151 expiration of the relevant patent exclusivity or that the agreement's
152 provision for entry of the nonreference drug product before the
153 expiration of any patent exclusivity means that the agreement is
154 procompetitive within the meaning of subparagraph (B) of subdivision
155 (3) of subsection (a) of this section,

156 (2) That any patent is enforceable and infringed by the nonreference
157 drug filer in the absence of a final adjudication binding on the filer of
158 those issues,

159 (3) That the agreement caused no delay in entry of the nonreference
160 drug filer's drug product because of the lack of federal Food and Drug
161 Administration approval of that or of another nonreference drug
162 product, or

163 (4) That the agreement caused no harm or delay due to the possibility
164 that the nonreference drug filer's drug product might infringe some
165 patent that has not been asserted against the nonreference drug filer or
166 that is not subject to a final and binding adjudication on that filer as to
167 the patent's scope, enforceability and infringement.

168 This subsection shall not be construed to preclude a party from
169 introducing evidence regarding subdivisions (1) to (4), inclusive, of this
170 subsection and shall not be construed to preclude the factfinder from
171 making a determination regarding said subdivisions based on the full
172 scope of the evidence.

173 (c) In determining whether the parties to the agreement have met
174 their burden under subdivision (3) of subsection (a) of this section, the
175 factfinder shall presume that the relevant product market is that market
176 consisting of the brand or reference drug of the company alleging patent
177 infringement and the drug product of the nonreference company
178 accused of infringement and any other biological product that is
179 licensed as biosimilar or is an AB-rated generic to the reference product.

180 (d) (1) The provisions of this section shall not modify, impair, limit or
181 supersede the right of any drug company applicant to assert claims or
182 counterclaims against any person under the antitrust laws or other laws
183 relating to unfair competition of the federal antitrust law or state law.

184 (2) If any provision of this section, an amendment made to this section
185 or the application of any provision or amendment to any person or
186 circumstance is held to be unconstitutional, the remainder of this
187 section, the amendments made to this section and the application of the
188 provisions of this section or amendments to any person or circumstance
189 shall not be affected.

190 (e) (1) (A) Each person that violates or assists in the violation of this
191 section shall forfeit and pay to the state a civil penalty sufficient to deter
192 violations of this section, as follows:

193 (i) If the person who violated this section received any value due to
194 that violation, an amount up to three times the value received by the
195 party that is reasonably attributable to the violation of this section, or
196 twenty million dollars, whichever is greater.

197 (ii) If the violator has not received anything of value as described in
198 subparagraph (A)(i), an amount up to three times the value given to
199 other parties to the agreement reasonably attributable to the violation of
200 this section, or twenty million dollars, whichever is greater.

201 (iii) For purposes of this subdivision, "reasonably attributable to the
202 violation" shall be determined by the state's share of the market for the
203 brand drug at issue in the agreement.

204 (B) Any penalty described in subparagraph (A) of this subdivision
205 shall accrue only to the state and shall be recovered in a civil action
206 brought by the Attorney General against any party to an agreement that
207 violates this section.

208 (2) Each party that violates or assists in the violation of this section
209 shall be liable for any damages, penalties, costs, fees, injunctions, or
210 other remedies that may be just and reasonable, as determined by the
211 court.

212 (3) If the state is awarded penalties under subparagraph (A) of
213 subdivision (1) of this subsection, it may not recover penalties pursuant
214 to subdivision (2) of this subsection. This section shall not be construed
215 to foreclose the state's ability to claim any relief or damages available in
216 subdivision (2) of this subsection, other than those that are penalties.

217 (4) An action to enforce a cause of action for a violation of this section
218 shall be commenced within four years after the cause of action accrued.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2021</i>	New section
Sec. 2	<i>October 1, 2021</i>	New section

GL *Joint Favorable*