

THE PHARMACEUTICAL  
INTELLECTUAL  
PROPERTY AND  
COMPETITION  
LAW REVIEW

Editor  
Daniel A Kracov

THE LAWREVIEWS

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# PREFACE

The pharmaceutical business is truly one of the most global industries, with many companies operating in dozens of countries with differing legal regimes and healthcare systems. In certain respects, the rules governing industry activities have largely become harmonised, such as in drug manufacturing and the conduct of clinical trials. However, in other areas the legal frameworks differ, and those nuances can require significant efforts to both optimise strategies and comply with requirements in local jurisdictions. In the areas of focus of this book – pharmaceutical intellectual property, including patent linkage and exclusivities, and related competition concerns – while general concepts may be shared across jurisdictions, it can be critically important to tailor approaches to the local legal environment.

Maximising the value of intellectual property can make the difference in deciding to pursue the development of an important new treatment, and in determining its sustained success in the marketplace. Similarly, a failure to carefully manage risks in dealings with competitors, such as generic and biosimilar companies, can result in huge civil and criminal liabilities. This is an area of significant enforcement activity around the world, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property, such as exclusivities, and drug pricing and affordability has been a constant source of political scrutiny, as well as patient and physician concern. With the ongoing covid-19 pandemic spurring an intense focus on intellectual property and pricing issues associated with vaccines and other needed treatments, the stakes have grown even higher.

Our objective in framing this volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of jurisdictions. I would like to thank the authors for their contributions to this edition of the *Pharmaceutical Intellectual Property and Competition Law Review*. They have produced what we believe is a very useful tool for managing global risks in this area.

**Daniel A Kracov**

Arnold & Porter  
Washington, DC  
August 2020

# UNITED STATES

*Daniel A Kracov, David K Barr, Peter J Levitas and Deborah L Feinstein<sup>1</sup>*

## I OVERVIEW

This chapter provides an overview of the United States' frameworks for drug and biologic approvals, exclusivities and patent linkages, as well as the processes for addressing intellectual property disputes associated with applications for generic and biosimilar products. We also provide an overview of how these processes and associated strategies may come under antitrust scrutiny. Overall, the complex US legal frameworks in these areas are designed to strike a balance between encouraging innovation while incentivising timely patent challenges and market entry of competitors.

## II LEGISLATIVE AND REGULATORY FRAMEWORK

In the US, the primary legislation governing the regulation of drug products is the Federal Food, Drug, and Cosmetic Act (the FD&C Act), codified at Title 21 of the US Code, while the primary legislation governing biologic products is the Public Health Service Act (the PHS Act), codified at Title 42 of the US Code. The Food and Drug Administration's (FDA) implementing regulations are published in Title 21, Chapter I of the Code of Federal Regulations. As discussed herein, Congress has also passed significant legislation to encourage innovation and incentivise development of new drug products, and to lower costs, including the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments), which amended the FD&C Act to establish the generic drug approval pathway, and the Biologics Price Competition and Innovation Act (BPCIA), which amended the PHS Act and established an abbreviated licensure pathway for biologic products.

In addition to incentives in the form of statutory exclusivities, the US patent system grants exclusive rights to make, use, sell or import into the US inventions for which a patent has been granted. Section 35 of the US Code governs the US Patent and Trademark Office (USPTO), and the rights and remedies available under the patent system. The Leahy-Smith America Invents Act, signed into law in 2011, amended Section 35 of the US Code to implement, among other changes, a first-to-file system. The nominal term of a US patent is 20 years from date of filing of the earliest priority application filed in the USPTO.<sup>2</sup>

In the US, participants in the pharmaceutical sector are also subject to the antitrust laws, which influence how participants may contract with each other, how they may enforce

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1 Daniel A Kracov, David K Barr, Peter J Levitas and Deborah L Feinstein are partners at Arnold & Porter. The authors would like to thank associates Elizabeth Trentacost, Monique N Boyce and Rebecca L Neubauer, and senior associate Matthew Tabas, for their contribution to this chapter.

2 35 USC Section 154.

and acquire patents, how they may settle litigation and how they may market their products, as well as how they act in regard to a number of other areas. The key antitrust laws impacting the pharmaceutical sector are: Section 1 of the Sherman Antitrust Act (15 USC Section 1), which bans unreasonable contracts or conspiracies in restraint of trade; Section 2 of the Sherman Antitrust Act (15 USC Section 2), which outlaws ‘monopolization or attempts at monopolizing any aspect of interstate trade or commerce’; Section 7 of the Clayton Antitrust Act (15 USC Section 18), which bans mergers or acquisitions that may ‘substantially lessen competition or tend to create a monopoly’; and Section 5 of the Federal Trade Commission Act (15 USC Section 45), which outlaws ‘unfair methods of competition’ and ‘unfair or deceptive acts or practices’.

### III NEW DRUGS AND BIOLOGICS – APPROVAL, INCENTIVES AND RIGHTS

#### i Drugs

##### *Overview*

To market a new prescription drug in the US, an applicant must submit a new drug application (NDA) to the FDA for the agency’s review and approval, and the agency must find that the drug is safe and effective for its intended use. There are two primary types of NDAs – a ‘505(b)(1)’ NDA and a ‘505(b)(2)’ NDA.<sup>3</sup> A 505(b)(1) NDA is an application that contains full reports of investigations that demonstrate that the drug is safe and effective, whereas a 505(b)(2) NDA is an application that contains full reports of safety and effectiveness, but where at least some of the information essential to approval comes from studies that were not conducted by or for the applicant, and for which the applicant does not have a right of reference.<sup>4</sup> A sponsor submitting a 505(b)(2) NDA can also can rely on the FDA’s previous finding of safety and efficacy for an approved drug or published literature, or both, subject to the patent certification and exclusivity provisions of Hatch-Waxman.<sup>5</sup> When an applicant submits an NDA for the FDA’s review, it must pay a ‘user fee’ to the agency.<sup>6</sup> As part of the establishment of user fees by Congress, the FDA sets corresponding review performance goals, including time lines for review after a two-month filing period – 10 months for standard review and six months for priority review – and goals for the percentage of applications to be reviewed.<sup>7</sup> The FDA seeks to expedite the development and review of applications for drugs and biologics that address an unmet medical need in the treatment of a serious or life-threatening condition, and administers four programmes to

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3 21 USC Section 355. The NDA pathway is primarily used for prescription drugs, though companies that intend to market an over-the-counter drug that does not comply with the terms of the applicable monograph may submit an NDA for the FDA’s review and approval.

4 21 USC Section 355(b)(1), (b)(2).

5 FDA Draft Guidance for Industry, Applications Covered by Section 505(b)(2) (Oct. 1999) at 2–3, [www.fda.gov/media/72419/download](http://www.fda.gov/media/72419/download).

6 21 USC Section 379h. The Prescription Drug User Fee Act (PDUFA), which authorises the FDA to collect fees from human drug and biologics companies must be reauthorised every five years.

7 See FDA, PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, [www.fda.gov/media/99140/download](http://www.fda.gov/media/99140/download).

facilitate this goal – fast-track designation,<sup>8</sup> breakthrough therapy designation,<sup>9</sup> accelerated approval<sup>10</sup> and priority review, as well as a special breakthrough programme for regenerative medicine advanced therapies.<sup>11</sup> Benefits of these programmes vary, and some are overlapping, but can include enhanced interaction with the FDA during the development process, and rolling review or a shorter review period, among other benefits.

### ***Exclusivity***

To incentivise drug development and reward innovation, the FD&C Act and the FDA's regulations provide for periods of data and marketing exclusivity.<sup>12</sup> This exclusivity can delay or prevent the review and approval of certain types of follow-on drug applications for a period of time, and may run concurrently with other types of exclusivity. Exclusivity differs from patent protection, and periods of exclusivity can run concurrently with patent terms. The FDA publishes information about a drug's exclusivity and patents in a publication typically referred to as the 'Orange Book'.<sup>13</sup>

#### *New chemical entity exclusivity*

An NDA is eligible for a period of a five-year new chemical entity (NCE) data exclusivity if the application contains a drug, 'no active ingredient (including any ester or salt of the active ingredient)' of which has previously been approved by the FDA in an NDA.<sup>14</sup> During this period of exclusivity, the FDA may approve neither a 505(b)(2) NDA or abbreviated new drug application (ANDA) that contains the same active moiety, nor may a 505(b)(2) NDA or ANDA for the same active moiety with a Paragraph IV patent certification be submitted

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8 21 USC Section 356(b).

9 21 USC Section 356(a).

10 21 USC Section 356(c). See also 21 CFR Part 314, subpart H.

11 FDA Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014), [www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf](http://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf); 21 USC Section 360n (Tropical Disease Priority Review Voucher); 21 USC Section 360ff (Rare Paediatric Disease Priority Review Voucher).

12 The FD&C Act and FDA regulations also provide for incentives to develop drugs for rare diseases (those that affect fewer than 200,000 people in the US), including rare diseases that affect paediatric populations. See, e.g., 21 USC, Part B – Drugs for Rare Diseases or Conditions; 21 CFR Part 316, Subpart C – Designation of an Orphan Drug. The FDA's Office of Orphan Products Development administers the Orphan Drug Designation Program and the Rare Paediatric Disease Priority Review Voucher Program. See FDA Office of Orphan Products Development, [www.fda.gov/about-fda/office-clinical-policy-and-programs/office-orphan-products-development](http://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-orphan-products-development). Designation of a drug as an 'orphan drug' provides drug sponsors with incentives such as tax credits for qualified clinical tests, waiver of prescription drug user fees and exclusivity.

13 FDA, Approved Drug Products with Therapeutic Equivalence Evaluations, [www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book](http://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book) (the Orange Book).

14 21 USC Section 355(c)(3)(E)(ii), (j)(5)(F)(ii). The FDA's regulations interpret an NCE as 'a drug that contains no active moiety that has been approved by FDA in any other NDA submitted under section 505(b)' of the FD&C Act. 21 CFR Section 314.108(a). An active moiety is 'the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . or other noncovalent derivative . . . of the molecule, responsible for the physiological or pharmacological action of the drug substance'. *id.*

for a period of at least four years, and in other cases five years, from the date of approval of the application.<sup>15</sup> The FDA may, however, review and approve a subsequent 505(b)(1) NDA that contains the same active moiety during the pendency of NCE exclusivity.

*‘Three-year’ new clinical investigation exclusivity*

A 505(b)(1) or 505(b)(2) NDA or efficacy supplement that contains a previously approved active moiety may be eligible for a three-year period of exclusivity if the application contains ‘reports of new clinical investigations (other than bioavailability studies)’ that are ‘essential to the approval of the application’ and were ‘conducted or sponsored by the applicant’.<sup>16</sup> During the exclusivity period, the FDA may not approve a subsequent 505(b)(2) NDA or an ANDA referencing that application that contains the same active moiety for the exclusivity-protected conditions of approval.<sup>17</sup> This exclusivity does not block a 505(b)(1) NDA, or block a subsequent 505(b)(2) NDA that does not seek approval for the exclusivity-protected indication or an ANDA that is permitted to ‘carve out’ the exclusivity-protected information from its labelling.

*Orphan drug exclusivity*

Drugs and biologics that receive orphan designation from the FDA prior to application submission and are approved for the orphan designated use may be eligible for a seven-year period of ‘orphan drug’ marketing exclusivity.<sup>18</sup> Unless the FDA has previously approved the ‘same drug for the same use or indication’, during the period of exclusivity, it may not approve another sponsor’s application for the ‘same drug’ for the ‘same use or indication’.<sup>19</sup> Orphan drug exclusivity protects only the approved indication or use of an orphan-designated drug.<sup>20</sup> Thus, if the approval was for a particular use or indication within the rare disease or condition, the FDA may subsequently approve a drug for uses or indications that are not exclusivity-protected.<sup>21</sup>

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15 21 CFR Section 314.108(b)(2). However, a 505(b)(2) NDA or an ANDA that contains the same active moiety may be submitted after four years if the application contains a certification of patent invalidity or non-infringement (a ‘Paragraph IV’ certification).

16 21 USC Section 355(c)(3)(E)(iii).

17 21 USC Section 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv); 21 CFR Section 314.108(b)(4)–(5).

18 21 USC Section 360cc(a); 21 CFR Section 316.31(a). The FDA’s regulations provide that an orphan-designated drug will receive exclusivity only if ‘the same drug has not already been approved for the same use or indication’. 21 CFR 316.3(a)(12). Where the FDA has previously approved the ‘same drug’ for the ‘same use or indication’, to be eligible for orphan drug exclusivity, the sponsor must demonstrate that its product is clinically superior to any previously approved drug that is the ‘same drug’. 21 USC Section 360cc(c). ‘Same drug’ is defined in the FDA’s regulations at 21 CFR Section 316.3(b)(14), and for a small molecule drug, it means a ‘drug that contains the same active moiety as the previously approved drug and is intended for the same use as the previously approved drug . . . except that if the subsequent drug can be shown to be clinically superior to the first drug, it will not be considered to be the same drug’. 21 CFR.

19 21 CFR Section 316.31(a). But see 21 CFR Section 316.31(a)(1)–(4), outlining conditions under which the FDA may approve a marketing application for the same drug during the pendency of orphan drug exclusivity.

20 21 CFR Section 316.31(b).

21 id.

### *Paediatric exclusivity*

A drug or biologic may be eligible for a six-month 'add-on' to new or existing exclusivities, or patent protection if the applicant performs a paediatric study<sup>22</sup> that is requested by the FDA and if the drug has a period of exclusivity or listed patent to extend (or in the case of a biologic, exclusivity).<sup>23</sup> This paediatric exclusivity applies not only to the product or indication that was studied in the paediatric population, but also to all of the applicant's formulations, dosages and indications for products that contain the same active moiety. During the six-month extension of exclusivity or patent protection, the FDA may not approve NDAs or ANDAs that are covered by the scope of the paediatric exclusivity without a label carve-out. For patent protection, paediatric exclusivity does not extend the term of the patent itself or the term of a patent extension, but rather the period during which the FDA cannot approve an ANDA or a 505(b)(2) NDA that certifies to a patent listed in FDA's Orange Book.

### *GAIN Act exclusivity*

Title VIII of the Food and Drug Administration Safety and Innovation Act, entitled the Generating Antibiotic Incentives Now (GAIN) Act, was implemented in Section 505E of the FD&C Act and provides for incentives to develop antibacterial and antifungal drug products to treat serious or life-threatening infections (qualified infectious disease products (QIDPs)). Drug products submitted in a 505(b)(1) or 505(b)(2) NDA or efficacy supplement that are designated as QIDPs prior to application submission and that are approved for the designated use are eligible for a five-year extension or add-on of exclusivity.<sup>24</sup> GAIN exclusivity can extend a period of NCE, three-year exclusivity or orphan drug exclusivity, and the GAIN exclusivity extension can be further extended by paediatric exclusivity.<sup>25</sup>

## **ii Generic drugs**

'Generic' drugs are approved by the FDA through the ANDA pathway, set forth in Section 505(j) of the FD&C Act, as amended by the Hatch-Waxman Amendments.<sup>26</sup> An ANDA must reference an approved 'reference listed drug' product, and relies on the FDA's finding of safety and efficacy for the drug, rather than providing independent evidence of safety and efficacy in the application. Subject to limited exceptions, the ANDA must contain the same active ingredient, conditions of use, route of administration, dosage form, strength and (with certain permissible differences) labelling as the listed drug upon which the

22 For purposes of paediatric exclusivity, a paediatric study means 'at least one clinical investigation (that at [the FDA's] discretion, may include pharmacokinetic studies) in paediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at [the FDA's] discretion, may include preclinical studies'. 21 USC Section 355a(a).

23 21 USC Section 355a(b)(2), (c)(2). Exclusivity that may be extended includes NCE, three-year, orphan drug, and GAIN. Patents that may be extended are those that claim the drug or a use for such drug that are or will be listed in the FDA's Orange Book. Products that are not eligible for exclusivity, products that do not have any remaining exclusivity or patent protection, and products that have nine or fewer months remaining in the term of exclusivity or patent protection at the time when the FDA accepts the paediatric study reports, are ineligible for paediatric exclusivity.

24 1 USC Section 355f(a); FDA Draft Guidance for Industry, Qualified Infectious Disease Product Designation Questions and Answers (Jan. 2018) at 5–6, [www.fda.gov/media/111091/download](http://www.fda.gov/media/111091/download).

25 See 21 USC Section 355f(a), (b).

26 21 USC Section 355(j).

application relies, and must demonstrate bioequivalence to such drug.<sup>27</sup> The FDA's review and approval of ANDAs may be prevented or delayed by exclusivity and patent protection for the listed drug that the ANDA references. Similar to prescription drug and biologics, generic drug applications are subject to user fees.<sup>28</sup> The FDA also publishes a commitment letter paired with the Generic Drug User Fee Amendments (GDUFA) authorisation, in which it sets goals for reviewing a certain percentage of ANDAs within a specific period, and may prioritise the review of certain ANDAs if they serve public health priority, meet a prioritisation factor outlined in the relevant Manual of Policies and Procedures (MAPP), or that are designated as a competitive generic therapy.<sup>29</sup>

ANDAs are eligible for two types of ANDA-specific exclusivity periods – 180-day 'patent challenge' exclusivity<sup>30</sup> and 180-day competitive generic therapy (CGT) exclusivity.<sup>31</sup> On the one hand, 180-day patent challenge exclusivity provides ANDA applicants with an incentive to challenge a listed drug's patents by providing 180 days of exclusivity to the first applicant that submits a substantially complete application containing a 'Paragraph IV' certification to the listed drug's patent or patents.<sup>32</sup> During the exclusivity period, which commences on the date of the first commercial marketing of the ANDA, the FDA may not approve an ANDA containing a Paragraph IV certification that references the same listed drug.<sup>33</sup> On the other hand, 180-day CGT exclusivity is intended to incentivise development of generic drugs that are not 'protected by patents or exclusivities and for which there is inadequate generic competition'.<sup>34</sup> It provides a 180-day period of exclusivity for the 'first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book' when the ANDA was submitted.<sup>35</sup> During this exclusivity period, which starts on the date of the first applicant's first commercial marketing, the FDA may not approve an ANDA that is the same as the CGT ANDA.<sup>36</sup>

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27 21 USC Section 355(j)(2)(A)(i)-(v), (j)(2)(C); 21 CFR Section 314.94(a). An example of differences in labelling is where the applicant is not seeking approval for a condition of use that is protected by patent or exclusivity. See 21 USC Section 355(j)(2)(A)(viii); 21 CFR Section 314.94(a)(8)(iv). Generic drugs may also differ from the listed drug in terms of inactive ingredients.

28 21 USC Section 379j-42.

29 GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022, [www.fda.gov/media/101052/download](http://www.fda.gov/media/101052/download); FDA Center for Drug Evaluation and Research, Manual of Policies and Procedures, MAPP 5240.3 Rev. 5 (Jan. 30, 2020), [www.fda.gov/media/89061/download](http://www.fda.gov/media/89061/download); and FDA Guidance for Industry, Competitive Generic Therapies (Mar. 2020) at 9, [www.fda.gov/media/136063/download](http://www.fda.gov/media/136063/download).

30 21 USC Section 355(j)(5)(B)(iv).

31 21 USC Section 356h(b)(3), (e)(2); 21 USC Section 355(j)(5)(B)(v).

32 There can be more than one first applicant, and that ANDA applicants can 'share first-applicant status'. FDA Draft Guidance for Industry, 180-Day Exclusivity: Questions and Answers (Jan. 2017) at 4, [www.fda.gov/media/102650/download](http://www.fda.gov/media/102650/download).

33 21 USC Section 355(j)(5)(B)(iv)(I).

34 FDA Guidance for Industry, Competitive Generic Therapies (Mar. 2020) at 3, [www.fda.gov/media/136063/download](http://www.fda.gov/media/136063/download).

35 id.

36 An ANDA that is the same drug as the CGT may be approved and commence marketing before the CGT commences marketing. id. at 13-14.

### iii **Biologics and biosimilars**

#### *Innovator (reference) biologics*

Unlike small molecule drugs that are approved under Section 505 of the FD&C Act, biologics are approved under Section 351 of the PHS Act.<sup>37</sup> Licences for such ‘reference’ biologics are obtained by submitting a biologics licence application (BLA) pursuant to Section 351(a) of the PHS Act and implementing regulations.<sup>38</sup> Approval of the BLA is based on a determination that the product is safe, pure and potent (the equivalent of safety and effectiveness for a drug), and the facility in which the product is manufactured, processed, packed or held meets standards designed to assure such safety, purity and potency.<sup>39</sup> The PDUFA user fees that apply to drugs also apply when a reference product BLA is submitted to the FDA for review. Likewise, the FDA’s review commitments outlined in the PDUFA commitment letter apply to reference product BLAs, as do the expedited development and review pathways (e.g., fast-track).<sup>40</sup>

Like drugs, biologic products are also eligible for periods of exclusivity. Significantly, the FDA may neither approve an application for a biosimilar or interchangeable biologic that references the innovator biologic (reference product exclusivity) during a 12-year period of exclusivity starting from the date of first licensure of the reference product,<sup>41</sup> nor receive a biosimilar or interchangeable biologic for review until four years after the date of the reference product’s first licensure.<sup>42</sup> However, the statute significantly limits ‘evergreening’ of products through the filing of subsequent supplemental applications for only minor changes in the product. Reference products that receive orphan designation are also eligible for seven years of orphan drug exclusivity, as described in Section III.ii ‘Orphan drug exclusivity’.<sup>43</sup> Reference products are also eligible for a six-month paediatric exclusivity add-on to existing reference product exclusivity or orphan drug exclusivity, whichever is longer.<sup>44</sup>

37 42 USC Section 262.

38 42 USC Section 262(a); 21 CFR Part 601.

39 42 USC Section 262(a)(2)(C). See also 21 CFR Section 601.2(d).

40 21 USC Section 356(a)-(c); 21 CFR Part 601, Subpart E.

41 42 USC Section 262(k)(7)(A). Exclusivity is not available for a biologic licensed under section 351(a) of the PHS Act if it is a supplement to the reference product, or a “subsequent application filed by the same sponsor or manufacturer of the biological product (or a licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.” 21 USC Section 262(k)(7)(C).

42 42 USC Section 262(k)(7)(B).

43 21 USC Section 360cc(a)(2). If the reference product also has 12-year exclusivity, FDA may not license the biosimilar or interchangeable biologic until the expiration of the orphan exclusivity or 12-year exclusivity, whichever period is later. FDA Draft Guidance for Industry, Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act (Aug. 2014) at 2, <https://www.fda.gov/media/89049/download>.

44 42 USC Section 262(m)(2), (m)(3).

***Biosimilar and interchangeable biologics***

The PHS Act, as amended by the BPCIA, provides for an abbreviated pathway for the ‘licensure of biological products as biosimilar or interchangeable’.<sup>45</sup> An application for a biologic product submitted under Section 351(k) must include information to demonstrate that:

- a* the biologic is highly similar to the reference product;
- b* the biologic and the reference product utilise the same mechanism of action for the conditions of use prescribed, recommended or suggested in the proposed labelling to the extent that the mechanism is known for the reference product;
- c* the conditions of use prescribed, recommended or suggested in the labelling for the biologic have been previously approved for the reference product;
- d* the route of administration, dosage form and strength of the biologic are the same as the reference product; and
- e* the ‘facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent’.<sup>46</sup>

A biosimilar licensed under Section 351(k) must be ‘highly similar to the reference product notwithstanding minor differences in clinically inactive components’ and have ‘no clinically meaningful differences’ from the reference product in terms of safety, purity and potency.<sup>47</sup> The FDA reviews the totality of the evidence in making a licensure determination for these products. Biosimilar and interchangeable biologic product applicants must also pay a user fee to the FDA in connection with submitting a licence application.<sup>48</sup>

A product deemed by the FDA to be an interchangeable biologic – which to date has not occurred – would need to meet additional statutory criteria for product evaluation and testing so that it can be, subject to state law, substituted for the reference product at the pharmacy level without involvement of the prescriber. An interchangeable product is expected to ‘produce the same clinical result as the reference product in any given patient’ and if the product is administered more than once to a person, ‘the risk in terms of safety or diminished efficacy of alternating or switching between use of the [interchangeable] product and the reference product is not greater than the risk of using the reference product without such alternation or switch’.<sup>49</sup> The first interchangeable biologic is eligible for a period of exclusivity during which the FDA shall not make a determination that a follow-on biosimilar product is interchangeable for any condition of use until the earlier of – (1) one year after the first commercial marketing of the first interchangeable biologic for a particular reference product; (2) 18 months after a final court decision on all patents in an infringement lawsuit against the first applicant of the first approved interchangeable biologic or dismissal of such case; or (3) 42 months after approval of the first interchangeable biologic if the first applicant

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45 42 USC Section 262(k).

46 42 USC Section 262(k)(2)(A)(i).

47 42 USC Section 262(i)(2).

48 21 USC Section 379j-52. The applicable user fees are known as biosimilar user fee amendment fees.

49 42 USC Section 262(k)(4).

has been sued for patent infringement and the litigation is still ongoing during the period, or 18 months after approval of the first interchangeable biologic if the first applicant has not been sued.<sup>50</sup>

#### IV PATENT RIGHTS AND PATENT TERM EXTENSIONS

Patents are a property right that is granted by the US Patent and Trademark Office to an invention related to a new drug or biologic product, including its composition, associated formulations, methods of manufacturing, and dosing or treatment regimens. The patent right grants its holder the right to exclude others from making, using, selling, offering for sale or importing the claimed invention. To be eligible for patent protection, the invention must be considered new, useful, non-obvious and directed to one of the statutory classes of patentable subject matter.<sup>51</sup> Courts in the United States have interpreted the statutory categories of invention to exclude laws of nature, natural phenomena and abstract ideas.<sup>52</sup> The patent includes a specification, which must include a written description of the invention and set forth the manner and process of making and using the invention such that a person of skill in the art would be enabled to practice the invention.<sup>53</sup> The patent must also include one or more 'claims' that distinctly point out the subject matter that the patent applicant regards as his or her invention.<sup>54</sup> A patent in the US is now granted to the first inventor to file an application, as opposed to the previous system that granted patent rights to the first party to invent. The grant of a patent right is separate from the grant of marketing exclusivity. As a patent may be granted anytime during the development of a drug product, periods of exclusivity and patent terms may or may not run concurrently.

The nominal term of a US patent is 20 years from date of filing of the earliest priority application filed in the USPTO.<sup>55</sup> A patent may be entitled to an additional term, called a patent term adjustment, to compensate for delays by the USPTO in examining the patent application in accordance with a statutory formula set out in 35 USC Section 154(b). Separately, upon FDA approval, a patent claiming a drug product or a method of using a drug product may receive a patent term extension (PTE), to accommodate for the time the drug product was subject to a regulatory review period.<sup>56</sup> The application for a PTE must be filed within 60 days of FDA approval of the drug product.<sup>57</sup> Only one patent may receive a PTE for any product subject to a regulatory review period<sup>58</sup> with the extent of the PTE governed by a statutory calculation based on one-half the number of days that the product was in clinical trials and the total number of days that the application for marketing approval was under review, less the number of days in the regulatory review period that were on and

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50 42 USC Section 262(k)(6).

51 35 USC Section 101, 102.

52 *Alice Corp Pty Ltd v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354, 110 USPQ2d 1976, 1980 (2014).

53 35 USC Section 112(a).

54 35 USC Section 112(b).

55 35 USC Section 154.

56 35 USC Section 156.

57 35 USC Section 156(d)(1); 37 CFR Section 1.720(f).

58 A PTE is available under 35 USC Section 154 for both small molecule drug products and large molecule biologic products approved under the BPCIA, provided that the 'permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use'. 35 USC Section 156(a)(5)(A).

before the date on which the patent was issued and also less the number of days that the applicant was not diligent in proceeding for approval.<sup>59</sup> A PTE cannot exceed 14 years after the date of regulatory approval or five years after the date of nominal patent expiration.<sup>60</sup>

## V PATENT LINKAGE

As explained in Section III.ii, the Hatch-Waxman Amendments provided for the approval of generic versions of innovator drugs by the filing of an ANDA. In 2009, the BPCIA was enacted to provide for the approval of biosimilar versions of innovator biologic drugs. Both statutes provide for a mechanism of litigating and resolving disputes raised by the innovator's patents prior to the launch of the generic or biosimilar product, although, as explained below, the mechanisms are very different.

### i Patent linkage under the Hatch-Waxman Amendments

Under 21 USC Section 355(b)(1), the owner of an NDA is required to 'file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug'. The patent information provided by the NDA owner is listed for the approved drug along with regulatory exclusivity information in the Orange Book.<sup>61</sup>

The listing of patents in the Orange Book facilitates the resolution of patent disputes raised by ANDA filers under 21 USC Section 355(j).<sup>62</sup> Generic applicants filing ANDAs are required to make one of the following four 'certifications' with respect to patents listed for the approved drug in question: '(i) that such patent information has not been filed, (ii) that such patent has expired, (iii) of the date on which such patent will expire, or (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted'.<sup>63</sup> The last of these is the Paragraph IV certification.

The filing of an ANDA with a Paragraph IV certification with regard to a patent is a statutory act of infringement of that patent under 35 USC Section 271(e)(2). It is sometimes referred to as an 'artificial' act of infringement because the generic company has not yet sold a product covered by any of the Orange Book-listed patents. Within 20 days of the FDA's acceptance of an ANDA containing a Paragraph IV certification, the ANDA applicant is required to provide written notice to the NDA owner and each owner of the challenged patents that the ANDA has been filed along with the ANDA filer's detailed basis for its opinion that any of the listed patents are invalid or will not be infringed.<sup>64</sup>

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59 See 37 CFR Section 1.775.

60 35 USC Section 156.

61 If a patent issues after NDA filing, but before approval, 'the applicant shall amend the application to include the information'. 21 USC Section 355(b)(1). Under the applicable regulations, the amendment is to be made within 30 days of patent issuance. 21 CFR Section 314.53(d)(1). If a patent issues after NDA approval, the NDA 'holder shall file such information . . . not later than thirty days after the date the patent involved is issued'. 21 USC Section 355(c)(2).

62 Essentially the same patent dispute resolution mechanism applies to 505(b)(2) NDAs.

63 21 USC Section 355(j)(2)(A)(vii).

64 21 USC Section 355 (j)(2)(B)(ii)-(iv).

In addition, ANDA applicants can also include a statement in their ANDAs that a listed patent claiming a method of use of an approved drug product does not claim a use for which the ANDA applicant is seeking approval.<sup>65</sup> The ANDA applicant then omits or ‘carves out’ the patented use from its proposed label for its generic product. In general, by using this ‘skinny’ label approach, the ANDA applicant may avoid a claim of infringement with respect to a patent claiming the use that has been carved out.

If the NDA owner files an infringement action within 45 days of the receipt of a Paragraph IV notice, FDA approval of the generic application is stayed for a period of 30 months while the patent dispute is litigated.<sup>66</sup> For new drugs that have NCE exclusivity (explained in Section III.i), the stay of FDA approval extends until seven and a half years after NDA approval.<sup>67</sup> A court may order that this period be shorter or longer ‘because either party to the action failed to reasonably cooperate in expediting the action’.<sup>68</sup>

The 30-month stay of generic approval provides time for the NDA owner and ANDA filer to litigate patent issues prior to final FDA approval of the ANDA and therefore prior to sales of the generic drug. The actions are generally tried to the court and not a jury because there are no monetary damages prior to generic launch. However, if the generic launches ‘at risk’ because, for example, the 30-month stay has expired, the case can be tried to a jury.

If an Orange Book-listed patent is held valid and infringed, the district court will order that the effective date of generic approval will be not be earlier than the expiration date of the patent. The district court can also grant injunctive relief to prevent the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States of the infringing product and can also award monetary damages if there has been a commercial sale of the generic product.<sup>69</sup>

Decisions of the district courts in Hatch-Waxman patent litigations are appealable to the United States Court of Appeals for the Federal Circuit.

## ii Patent linkage under the BPCIA

Like the Hatch-Waxman Amendments, the BPCIA provides for a mechanism for innovator companies and biosimilar applicants to litigate patent disputes prior to the commercial sale of the biosimilar product. The filing of an application for a biosimilar version of an innovator biologic product is also an artificial act of infringement and the innovator company has available to it essentially the same remedies if such infringement is proven.<sup>70</sup> However, the patent dispute resolution mechanism for biosimilar applicants, set out in 42 USC Section 262(1), is very different from the mechanism under the Hatch-Waxman Amendments.

The BPCIA does not provide for the listing of patents by the innovator of a biologic product (reference product sponsor (RPS)) in an FDA publication (the FDA has developed a ‘Purple Book’ that lists licensed biologics and biosimilars, and their corresponding exclusivities), so there is no public notice to potential biosimilar applicants of patents that the innovator deems relevant to the biologic product in question. Instead, the BPCIA provides a mechanism that commences when the biosimilar applicant provides a copy of its application

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65 21 USC Section 355(j)(2)(A)(viii).

66 21 USC Section 355(j)(5)(b)(3).

67 21 USC Section 355(j)(5)(F)(2).

68 21 USC Section 355(j)(5)(b)(3).

69 35 USC Section 271(e)(4).

70 35 USC Section 271(e)(2), (e)(4), (e)(6).

to the RPS under a confidentiality arrangement.<sup>71</sup> Within 60 days of receipt of a biosimilar application, the RPS provides a list of patents for which it ‘believes a claim of patent infringement could be reasonably asserted’ against the biosimilar product.<sup>72</sup> Thereafter, the BPCIA provides for a multi-step phased process by which the parties provide infringement and validity contentions with regard to the listed patents,<sup>73</sup> and exchange further lists of patents with a goal of reaching agreement on a list of patents that the parties will litigate with respect to the biosimilar applicant’s proposed product.<sup>74</sup> If the parties reach agreement on the patents to be litigated, the RPS then has 30 days within which to file suit.<sup>75</sup> If the parties do not reach agreement, they engage in a final exchange of lists.<sup>76</sup> While in this process, the biosimilar applicant controls the number of patents that will be litigated, the RPS will be able to file suit on at least one of its patents within 30 days after the final exchange of lists.<sup>77</sup>

Due to the number of steps provided by the BPCIA, the process has come to be known as the ‘patent dance’, which, if carried out to completion, lasts approximately 250 days. As described above the process initially permits the biosimilar applicant to control the number of patents owned or controlled by the RPS that will be litigated, although the RPS will be permitted under the process to sue on at least one of its patents.<sup>78</sup> However, the BPCIA also requires that the biosimilar applicant provide a 180-day notice of commercial marketing, following which the RPS may seek a preliminary injunction to prevent commercial sale by the biosimilar applicant with respect to any of the patents the RPS included on its initial list, but were not included in the litigation resulting from the patent dance procedure.<sup>79</sup> Accordingly, the BPCIA procedures provide for the possibility of two phases of potential patent litigation, a first phase under which the biosimilar applicant can limit the litigation to a single RPS patent, and a second phase under which the RPS can bring a suit on its remaining patents that it initially listed.

In *Sandoz, Inc v. Amgen, Inc* (2017),<sup>80</sup> the US Supreme Court held that a biosimilar applicant cannot be required to provide its biosimilar application to the RPS and can therefore forgo the patent dance procedure. However, a biosimilar applicant that does not provide the RPS with its application is subject to an immediate declaratory judgment action by the RPS

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71 42 USC Section 262(l)(1).

72 42 USC Section 262(l)(3). Under 35 USC Section 271(e)(2)(C)(i), the filing of the application becomes an act of infringement of the patents the RPS includes on its list under 42 USC Section 262(l)(3). See *Sandoz, Inc v. Amgen, Inc*, 134 S.Ct. at 1664, 1673. If the RPS omits a patent that ‘should have been included’ on its initial patent list, it may not bring an action for infringement of that patent with respect to the biological product. 35 USC Section 271(e)(6)(C). This provision encourages the RPS to be expansive on the patents it includes on its list at the outset of the patent exchange process. If there are newly issued or licensed patents, the RPS can add such patents to its list within 30 days after issuance or in-licensing. 42 USC Section 262(l)(7).

73 42 USC Section 262(l)(3)(B) and (C).

74 42 USC Section 262(l)(4).

75 42 USC Section 262(l)(6)(A).

76 42 USC Section 262(l)(5)(B).

77 42 USC Section 262(l)(5)(A) and (B)(ii); 42 USC Section 262(l)(B).

78 42 USC Section 262(l)(6)(B).

79 42 USC Section 262(l)(8).

80 134 S.Ct. 1664 (2017).

on any patent that ‘claims the biological product or the use of the biological product’.<sup>81</sup> In the same decision, the Supreme Court held that a biosimilar applicant may provide its 180-day notice of commercial marketing before the FDA licenses its biosimilar product.

Under 35 USC Section 271(e)(4), if the RPS prevails in a patent litigation on a patent, it may be awarded the same remedies as an NDA owner in Hatch-Waxman litigation; namely the district court will order that the effective date of generic approval will be not be earlier than the expiration date of the patent, and the district court can also grant injunctive relief to prevent the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States of the infringing product. As in the Hatch-Waxman Amendments, monetary damages can only be awarded if there has been a commercial sale of the generic product. If the RPS fails to bring a suit on any patent included on the negotiated list under 42 USC Section 262(l)(4) or (5) within the specified 30-day period, the RPS is limited to a reasonable royalty as its sole and exclusive remedy for infringement of that patent.<sup>82</sup>

Decisions of the district courts in BPCIA patent litigations are appealable to the United States Court of Appeals for the Federal Circuit.

## VI COMPETITION ENFORCERS

US antitrust laws<sup>83</sup> can be enforced by the federal government, state governments and by private parties injured by an alleged antitrust violation. Federal enforcement in the United States is shared by the US Department of Justice, Antitrust Division (DOJ) and the US Federal Trade Commission (FTC).<sup>84</sup> The DOJ and the FTC split antitrust enforcement regarding merger control and civil anticompetitive conduct largely by industry, with the FTC handling both merger control and civil anticompetitive conduct for the pharmaceutical sector.<sup>85</sup> The DOJ is responsible for criminal antitrust enforcement in all industries, including the pharmaceutical sector.

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81 42 USC Section 262(l)(9)(C). Under 35 USC Section 271(e)(2)(C)(ii), the filing of the application becomes an act of infringement with respect to the patents that the RPS could have listed under 42 USC Section 262(l)(3). See *Sandoz v. Amgen*, 134 S.Ct. at 1673 Under the BPCIA, the RPS cannot bring a declaratory judgment action against a biosimilar applicant that does provide its application and engages in the steps of the patent dance. However, if the biosimilar applicant fails to complete an action in the patent dance, the RPS can file a declaratory judgment action with respect to any of the patents it included on its initial list. 42 USC Section 262(l)(9)(A–C).

82 35 USC Section 271(e)(6)(B).

83 US antitrust laws include: Section 1 of the Sherman Antitrust Act, 15 USC Section 1, which bans unreasonable contracts or conspiracies in restraint of trade; Section 2 of the Sherman Antitrust Act, 15 USC Section 2, which outlaws ‘monopolization or attempts at monopolizing any aspect of interstate trade or commerce’; Section 7 of the Clayton Antitrust Act, 15 USC Section 18, which bans mergers or acquisitions that may ‘substantially lessen competition or tend to create a monopoly’; and Section 5 of the Federal Trade Commission Act, 15 USC Section 45, which outlaws ‘unfair methods of competition’ and ‘unfair or deceptive acts or practices’.

84 Only the FTC has the authority to enforce the FTC Act. The DOJ, state governments and private parties are not permitted to bring a suit under the Act.

85 The FTC sometimes works with the FDA to identify potentially anticompetitive conduct in the pharmaceutical sector.

Individual state attorneys general also have civil antitrust enforcement powers in the pharmaceutical sector. State attorneys general can bring actions under federal antitrust laws regarding conduct occurring in or affecting their state and have power to enforce their individual states' own antitrust laws.<sup>86</sup>

Private plaintiffs may enforce federal antitrust laws by filing civil action claims against parties for violating the antitrust laws.<sup>87</sup>

## VII MERGER CONTROL

Federal enforcers, state enforcers and private parties have standing to challenge mergers or acquisitions affecting interstate commerce under Section 7 of the Clayton Act.<sup>88</sup> A transaction violates Section 7 of the Clayton Act if it may substantially lessen competition. In general, an actionable harm to competition may occur if, post-transaction, the combined firm has the ability and incentive to raise prices, decrease supply, reduce innovation or product quality – either unilaterally or in coordination with other firms – or harm competition by foreclosing competitors from supply inputs or outlets for their products.<sup>89</sup> Potential harms to competition are more likely to occur if the parties already compete, or are likely to compete in the future.<sup>90</sup>

Merger analysis focuses on competitive effects within defined product and geographic markets. Product markets are defined around products and their substitutes, usually by application of the 'hypothetical monopolist' test (HMT). The HMT includes in a product market the products to which a consumer would switch in response to a small price increase by a hypothetical monopolist of one product. In the pharmaceutical industry, this has resulted in a variety of product market definitions, sometimes limited to a narrow market, including only a branded drug and its generic equivalents or biosimilars, or even just a market of generic drugs. In other cases, the market may include all drugs that treat a given indication using a particular mechanism of action or even more broadly as all drugs used to treat the indication.<sup>91</sup> Product markets may also include products still in the research and development stage that may compete in the future.

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86 Depending upon the state, the attorney general may enforce the antitrust laws seeking relief on behalf of the state itself or as a representative of the people (i.e., as *parens patriae*) or both.

87 15 USC Section 15.

88 15 USC Section 18. The Hart-Scott-Rodino Antitrust Improvements Act of 1976 requires parties to transactions meeting certain criteria to file pre-merger notifications with both the FTC and the DOJ. 15 USC Section 18(a).

89 For both 'horizontal' mergers (i.e., mergers among companies at the same level of the supply chain) and 'vertical' mergers (i.e., mergers among companies at different levels of the supply chain), the 'substantial lessening of competition' standard is implemented through the application of the federal antitrust authorities' Horizontal Merger Guidelines and Vertical Merger Guidelines. See U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines (2010) (the Horizontal Guidelines), [www.justice.gov/atr/horizontal-merger-guidelines-08192010](http://www.justice.gov/atr/horizontal-merger-guidelines-08192010) and U.S. Dep't of Justice & Fed. Trade Comm'n, Draft Vertical Merger Guidelines (2020), [www.justice.gov/opa/press-release/file/1233741/download](http://www.justice.gov/opa/press-release/file/1233741/download).

90 The competitive analysis also includes an assessment of whether any efficiencies from the transaction would outweigh any potential anticompetitive effects.

91 Compare Complaint at 2, *In the Matter of Teva Pharmaceutical Industries Ltd, and Allergan PLC*, Docket No. C-4589 (Fed. Trade Comm'n Sept. 15, 2016), [www.ftc.gov/system/files/documents/cases/160915teva-allergan-cmpt.pdf](http://www.ftc.gov/system/files/documents/cases/160915teva-allergan-cmpt.pdf) (defining product market by the molecule, which refers to the equivalency of brands and generics) with Complaint at 2, *In the Matter of Bristol-Myers Squibb Company*

If the merging parties' products compete now or may in the future, the antitrust authorities then examine whether any loss of competition from the transaction is likely to result in anticompetitive effects. This includes analysing the parties' and other competitors' market shares and the levels of market concentration both pre- and post-merger. In addition, the antitrust authorities will consider whether entry or expansion by third parties would be timely, likely and of a sufficient magnitude to offset any competitive harm arising from the transaction.

Finally, if the antitrust authorities determine a transaction is likely to result in anticompetitive effects, they will then consider whether the transaction will lead to cognisable efficiencies that would offset any competitive harm.<sup>92</sup> To be cognisable, efficiencies must be both merger-specific and verifiable.<sup>93</sup>

## VIII ANTICOMPETITIVE BEHAVIOUR

### i Patents and antitrust law

Patent law provides pharmaceutical patent owners (in most cases, branded drug companies) with the limited right to exclude others, but does not exempt them from antitrust scrutiny. Pharmaceutical patent owners have been the subject of litigation in a number of cases regarding alleged anticompetitive conduct through various means, including, but not limited to: reverse-payment settlements, product switching, brand-for-generics strategies (B4G), sham litigation and bundled discounts. These examples are not exhaustive; indeed, there may be other antitrust theories of harm advanced by both antitrust authorities and private plaintiffs.

### ii 'Reverse payment' settlements

The Hatch-Waxman Act creates a framework for generic drug companies to challenge patents quickly.<sup>94</sup> It also provides generic companies with a research exemption to develop generic drugs lawfully while the original brand's patent is still in effect.<sup>95</sup>

Patent disputes between branded and generic companies often settle. These settlements commonly involve the parties negotiating entry dates for the generic product, either at or before the branded drug's loss of exclusivity (LOE), based on anticipated litigation costs and respective litigation risk assessments. In 'reverse payment' settlements, the plaintiff branded drug company pays the defendant generic drug company as part of the settlement.<sup>96</sup> In *FTC v. Actavis*, the Supreme Court held that reverse payment settlements are subject to antitrust scrutiny because they may harm competition by delaying the entry of the generic

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*and Celgene Corp*, Docket No. C-4690 (Fed. Trade Comm'n Jan. 13, 2020), [www.ftc.gov/system/files/documents/cases/191\\_0061\\_c4690\\_bms\\_celgene\\_complaint\\_0.pdf](http://www.ftc.gov/system/files/documents/cases/191_0061_c4690_bms_celgene_complaint_0.pdf) (defining product market by the indication or method of action).

92 Horizontal Guidelines at 30.

93 *id.*

94 21 USC Section 355; 35 USC Section 271(e)(1).

95 21 USC Section 355(c)(3)(D)(i)(I)(aa), (j)(5)(C)(i)(I)(aa), and 35 USC Section 271(e)(5); 21 USC Section 355(e)(3)(C) and (j)(5)(B)(iii); FDA Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs are Submitted on the Same Day (July 2003) at 2, [www.fda.gov/media/71304/download](http://www.fda.gov/media/71304/download).

96 See *FTC v. Actavis, Inc*, 570 U.S. 136, 136-37 (2013).

competitor.<sup>97</sup> Lower courts have extended *Actavis* to non-cash ‘payment’ consideration,<sup>98</sup> such as an agreement by the branded drug company not to launch an authorised generic for a period of time.<sup>99</sup>

### iii Product switching

Product switching (product hopping) may occur when a branded drug company reformulates a branded drug at or near LOE, and encourages patients and doctors to switch to the new product.<sup>100</sup> Product switching can be either a ‘soft switch’ (when the original drug remains available to patients) or a ‘hard switch’ (when the original drug is made unavailable or significantly more difficult for patients to obtain).

While introduction of a new and improved product is not unlawful, a hard switch that removes the older product from the market may create significant antitrust risk because it can eliminate demand for the original branded drug before generics can enter the market and thus exclude generic competition.<sup>101</sup>

### iv B4G

A B4G strategy includes offering to a pharmaceutical benefit programme deeper discounts on branded drugs at or near LOE in exchange for preferred formulary placements. B4G strategies can be pro-competitive and pro-patient because they reduce prices of branded drugs for consumers, but they also may create antitrust risk to the extent that the brand goes beyond securing formulary placement by offering lower prices and contractually limits competition from generic drugs. Other market circumstances can affect the antitrust risk from B4G strategies; for example, risk may be higher when customer co-pays are higher for branded drugs than for the non-preferred generic (usually because the customer’s pharmaceutical benefit programme requires a higher co-pay for branded products) or if agreements between a branded manufacturer and pharmaceutical benefit programs are long-term and cover a substantial portion (at least 30 per cent) of a given market.

### v Sham petitioning and litigation

Under the *Noerr-Pennington* doctrine, parties are generally immune from liability under antitrust laws for engaging in actions to influence government decision-making (e.g., government petitioning, lobbying and litigation), even if the action they are seeking would

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97 id. at 154–58.

98 See *King Drug Co of Florence, Inc v. Smithkline Beecham Corp*, 791 F.3d 388, 409 (3d Cir. 2015) (holding that an agreement by the branded drug company not to launch an authorised generic for a period of time was considered a large and unjustified reverse payment) and *Rochester Drug Co-Operative, Inc v. Warner Chilcott Co (In re Loestrin Fe Antitrust Litig)*, 814 F.3d 538, 552 (1st Cir. 2016) (‘Although the value of non-cash reverse payments may be much more difficult to compute than that of their cash counterparts . . . antitrust litigation already requires courts to make intricate and complex judgments about market practices’), which overturned district court rulings that *Actavis* only applied to cash payments. See also *In re Lipitor Antitrust Litig*, 46 F. Supp. 3d 523, 543 (D.N.J. 2014) (‘non-monetary payment must be converted to a reliable estimate of its monetary value’ using ‘a reliable foundation used within the industry’).

99 See *King Drug Co of Florence, Inc*, 791 F.3d at 409.

100 id.

101 See *New York v. Actavis PLC*, 787 F.3d 638, 654 (2d Cir. 2015) (finding ‘hard switch’ unlawful because ‘when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition its actions are anticompetitive under the Sherman Act’) (internal citation omitted).

limit competition.<sup>102</sup> However, branded drug companies may face antitrust liability for engaging in such conduct if their actions were a sham. Litigation will be found a sham only if the claim is ‘objectively baseless’ and – if baseless – the litigation itself, rather than the outcome of the litigation, harms the competitor.<sup>103</sup> Similarly, petitioning of regulatory bodies will be found a sham only if the arguments made are ‘objectively and subjectively baseless’ and the petitioning itself harms the competitor (e.g., through delaying introduction of a competing product while the FDA considers a ‘citizen petition’).<sup>104</sup>

## vi Bundled discounts

Companies sometimes offer discounts for purchasing multiple types of products at one time.<sup>105</sup> This strategy is often pro-competitive because it lowers prices.<sup>106</sup> However, a bundling strategy can create antitrust risk if it makes it more difficult for a seller of only one of the bundled products to compete, in particular if the bundling competitor is forced to sell the bundled products below cost to be able to compete with the bundle.<sup>107</sup>

## IX OUTLOOK AND CONCLUSIONS

In recent years, there has been an intense focus in the United States on the pricing of drug and biologic products, as well as competition in the pharmaceutical marketplace. In the coming years, we can expect significant new legislation and legal scrutiny of the industry in these areas. That said, while the ongoing covid-19 pandemic, and the government’s huge associated investment in vaccine and drug manufacturing, has renewed the focus on intellectual property and pricing, it has also highlighted the importance of pharmaceutical innovation. While there is significant bipartisan interest in these issues, the prescriptions for addressing them vary greatly from a political perspective, and the upcoming US election could have major implications in this area.

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102 See *E RR Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127, 136 (1961). The *Noerr* doctrine states that acts of initiating litigation and other means of petitioning the government are immune from federal antitrust laws, even if these acts may lead to a monopoly or restraint on trade.

103 *Professional Real Estate Investors, Inc v. Columbia Pictures Indus, Inc* 508 U.S. 49, 50 (1993).

104 *In re DDAVP Direct Purchaser Antitrust Litig*, 585 F.3d 677, 694 (2d Cir. 2009).

105 See, e.g., *Collins Inkjet v. Eastman Kodak Co*, 781 F.3d 264, 274 (6th Cir. 2015) (affirming the lower court ruling to enjoin Kodak’s policy to charge lower prices for printers to customers who also bought Kodak brand ink).

106 See, e.g., *Atl Richfield Co v. USA Petrol Co*, 495 U.S. 328, 340 (1990) (‘Low prices benefit consumers regardless of how those prices are set, and so long as they are above predatory pricing levels, they do not threaten competition’); *Collins Inkjet*, 781 F.3d at 271 (‘Competitive sellers generally aim to make their products significantly cheaper than their competitors, and there is nothing inherently wrong with doing so via differential pricing’); *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 894-96 (9th Cir. 2008) (‘[W]e should not be too quick to condemn price-reducing bundled discounts as anticompetitive, lest we end up with a rule that discourages legitimate price competition’).

107 See *Cascade Health Sols v. PeaceHealth*, 515 F.3d at 899 (describing the ‘discount attribution test’ asking whether an equally efficient competitor offering only a single product could profitably match the total discount offered on the bundle); *Eisai v. Sanofi Aventis*, Civ. Action No. 08-4168 (MLC), 2014 U.S. Dist. LEXIS 46791 (D.N.J. March 28, 2014) (holding that bundling is anticompetitive when it forecloses portions of the market to a potential competitor who ‘does not manufacture an equally diverse group of products [and who therefore] cannot make a comparable offer’); *SmithKline Beecham Corp. v. Abbott Labs*, No. C 07-5702 CW, 2014 U.S. Dist. LEXIS 164367 (N.D. Cal. Nov. 24, 2014).

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