ARNOLD & PORTER LLP

US Healthcare Reform:
Impact on the Canadian Life Sciences Industry

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THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

(as amended by Healthcare and Education Reconciliation Act --HERCA)

THE PATIENT PROTECTIONS AND AFFORDABLE CARE ACT

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General Approach to Expanding Access to Health Care Services

- Require most U.S. citizens and legal residents to have health insurance.
  - Create state-based American Health Benefit Exchanges through which individuals can purchase coverage, with premium and cost sharing credits available to individuals/families with income between 133-400% of the federal poverty level (the poverty level is $18,310 for a family of three in 2009) and create separate Exchanges through which small businesses can purchase coverage.
  - Require employers to pay penalties for employees who receive tax credits for health insurance through an Exchange, with exceptions for small employers. Impose new regulations on health plans in the Exchanges and in the individual and small group markets.
  - Expand Medicaid to 133% of the federal poverty level.

A FEW IMPORTANT MEDICARE PROVISIONS

Eliminate the Part D Donut Hole

- Phases in coverage in the Medicare Part D drug benefit coverage gap, or "doughnut hole."
  - In 2010, Part D enrollees with any spending in the coverage gap will receive a $250 rebate.
  - Beginning in 2011, enrollees with spending in the coverage gap will receive a 50 percent discount on brand-name drugs, provided by the pharmaceutical industry. The law phases in Medicare coverage in the gap for generic drugs beginning in 2011, and for brand-name drugs beginning in 2013.
  - By 2020, Part D enrollees will be responsible for 25 percent of the cost of both brands and generics in the gap, down from 100 percent in 2010. The catastrophic coverage threshold is reduced between 2014 and 2019.

Improves Coverage for Preventive Services

- Beginning in 2011, no coinsurance or deductibles will be charged in traditional Medicare for preventive services that are rated A or B by the U.S. Preventive Services Task Force (USPSTF).
- Medicare will cover a free annual comprehensive wellness visit and personalized prevention plan.

Payment and Delivery System Reforms

- Plot program to bundle payments for post-acute care, value-based purchasing for providers, and the establishment of accountable care organizations.
- Creates new Center for Medicare and Medicaid Innovation within CMS to test new payment and service delivery models, and establishes a new Federal Coordinated Health Care Office within CMS to improve the integration of care for beneficiaries eligible for both Medicare and Medicaid (the dual eligibles).
- Reduces annual market basket updates for inpatient and outpatient hospital services, long-term care hospitals, and inpatient rehabilitation facilities and psychiatric hospitals and units, home health agencies, skilled nursing facilities, hospices, and other Medicare providers.

Payment and Delivery System Reforms (cont'd.)

- Establishes a hospital value-based purchasing program in Medicare to pay hospitals based on performance on quality measures, beginning in 2012. Requires the Secretary to establish quality reporting initiatives for long term care hospitals, inpatient rehabilitation hospitals, hospice programs, psychiatric hospitals, and PPS-exempt cancer centers, effective October 1, 2012.
- Requires the Secretary to develop plans to implement value-based purchasing programs for skilled nursing facilities and home health agencies (beginning October 1, 2011) and ambulatory surgical centers (beginning January 1, 2011).

Medicare Advantage Changes

- Currently, MA plans receive payments from the federal government to provide Medicare-covered benefits based on a statutory formula; payments vary by county.
  - Medicare payments to Medicare Advantage plans are currently higher, on average, than local fee-for-service costs. Plans receive 75 percent of the difference between the plan bid and the benchmark in the form of a rebate.
- Restructures payments to Medicare Advantage plans by setting payments closer to the average costs of Medicare beneficiaries, by county. Between 2012 and 2013 most plan benchmarks will gradually be reduced to levels closer to the costs of enrollees in traditional Medicare in each county.

MEDICAID REBATES

Before Health Reform

- Medicaid rebate for innovator drugs = basic rebate + additional rebate.
- Basic rebate = greater of 15.1% of AMP or AMP – Best Price (BP).
- Rebate for non-innovator drugs = 11% of AMP.
- No Medicaid rebates owed on MCO utilization.

Increase in Minimum Rebate

- Minimum rebate for innovator drugs generally increases to 23.1% of AMP.
  - Exception: only increases to 17.1% of AMP for certain clotting factors and drugs "approved by the [FDA] exclusively for pediatric indications."
- Rebate for generic drugs increases to 13% of AMP.

340B PROGRAM

340B Expansion

- ACA expands 340B eligibility to
  - Certain children's hospitals and free standing cancer hospitals excluded from the Medicare prospective payment system;
  - Critical access hospitals;
  - Rural referral centers; and
  - Sole community hospitals.
- Interpretive issue created because certain children's hospitals already were eligible to participate in 340B.
- Orphan drugs not required to be sold at or below the 340B ceiling price to the new categories of covered entities.

340B Program Integrity Provisions

- Creates extensive new requirements for manufacturers.
- Manufacturers will report 340B ceiling prices to HRSA on a quarterly basis.
- Current Law
  - No CMPs specific to 340B pricing (but Medicaid rebate CMPs could apply).
- ACA
  - CMPs would not exceed $5,000 for each "knowing and intentional" instance "of overcharging a covered entity that may have occurred."

KEY COMMISSIONS AND INITIATIVES

Key Commissions and Initiatives

- Independent Payment Advisory Board
  - 15 member board appointed by the President with "advice and consent" of the Senate
  - 6 year term, FT position, SES salary ($165,000)
  - GAO will appoint a 10-member Consumer Advisory Council to advise the IPAB
  - First proposals may be submitted as of Jan. 15, 2014
  - GAO study on the impact of the IPAB by July 2015
- Patient-Centered Outcomes Research Institute (PCORI)
  - Comparative effectiveness research
  - Tax-exempt independent government corporation overseen by a board of governors that includes the directors of the Agency for Health Care Research and Quality (AHRQ) and the National Institutes of Health (NIH).

PCORI/Comparative Effectiveness (cont'd.)

- Plus 17 members appointed by the Comptroller General (U.S. Government Accountability Office), including 3 members representing drug/device manufacturers
- Comparative clinical effectiveness research means research that evaluates and compares the patient health outcomes and benefits of two or more medical treatments or services. Such treatment and services are defined broadly to include protocols for treatment, care management and delivery; procedures; diagnostic tools; medical devices; therapeutics; and any other strategies used to treat, diagnose or prevent illness or injury.

PCORI/Comparative Effectiveness (cont'd.)

- The PCORI is responsible for setting national clinical comparative effectiveness research priorities and is directed to enter into contracts to manage the funding and conduct of research, with preference given to AHRQ and NIH.
- The PCORI will be responsible for establishing a standing research methodologies committee to develop standards for clinical comparative effectiveness, but the PCORI will conduct no research itself.
- Also has authority to appoint advisory panels.

Key Commissions and Initiatives (cont'd.)

- CMS Center for Medicare and Medicaid Innovation
  - Will test innovations in health care delivery
  - Must be operational by Jan. 2011, first report to Congress 2012
  - Must seek input from experts through public mechanisms
- Advisory Board for State Cooperatives
  - Advise on the establishment of loans and grant programs to support creation of non-profit health insurance issuers for the individual and small group markets
- Advisory Board for multi-state qualified health plans
  - Director established to provide recommendations of the multi-state qualified health plans. Membership is to be comprised of enrollees in such plans.

Key Commissions and Initiatives (cont'd.)

- Institute of Medicine Studies on Variation and the National Summit on Variation
- National Quality Strategy
  - Initial strategy design to be submitted to Congress Jan. 2011
- Assessment of Medicaid Policies
  - To be conducted by MACPAC in consultation with MedPAC

FRAUD AND ABUSE ENHANCEMENT

PPACA Fraud & Abuse Provisions

- Establishes procedures for screening, oversight, and reporting requirements for providers and suppliers that participate in Medicaid, Medicare, and CHIP.
- Increased funding for prevention and enforcement
- Return of overpayments within 60 days
- Civil monetary penalty changes
- Anti-Kickback Statute (AKS)
  - Prohibits knowingly and willfully providing anything of value with intent to induce or reward purchasing or prescribing of federally reimbursable products
    - ACA eliminates requirement of "actual knowledge" of the AKS violation or specific intent to violate the act

PPACA False Claims Act (FCA) Changes

- Expands FCA requirements beyond FERA
  - Expands ability of whistleblowers to sue by narrowing bar against suits based on public information
  - Expands the term “relator” to include individuals who can add materially to publicly disclosed information
  - Allows FCA suits to proceed based on public information if government requests
- May require return of overpayments
  - May result in FCA issue if fail to return payments from Medicare, Medicaid or other government programs within 60 days
- Specifically provides that violation of the AKS can establish “falsity” of a claim under False Claims Act (the “implied certification” theory)

TRANSPARENCY REPORTING

Transparency Reporting -- Timeline

- PPACA Sec. 6002 requires reporting of payments to covered recipients (U.S. physicians and teaching hospitals), and ownership interests.
- PPACA Sec. 6004 requires reporting of drug sample information.
- Timing of Implementation:
  - Not later than *October 1, 2011*, the Secretary of HHS must provide guidance on the definitions of terms and "establish procedures" for the submission and posting to the internet of physician payment information.
  - First report on payments and ownership interests due *March 31, 2013*, based on transactions that occurred in 2012, and then annually
  - Section 6004 - - first report on drug sample information is due in 2012 (not later than *April 1, 2012*).

Transparency Reporting Requirements

- PPACA requires an "**applicable manufacturer**" of a "**covered drug, device, biological, or medical supply**" that provides "**payments or other transfers of value**" to a "**covered recipient**" (or to an entity or individual at the request of or designated on behalf of a covered recipient) to submit "Transparency Reports" about those payments to HHS
- Reports will be submitted to HHS electronically

Key Definitions

- Applicable Manufacturer
  - "A manufacturer of a covered drug, device, biological, or medical supply, which is operating in the United States, or in a territory, possession, or commonwealth of the United States."
- Covered Drug, Device, or Medical Supply
  - "Any drug, biological product, device, or medical supply for which payment is available under title XVIII [Medicare] or a State plan under title XIX [Medicaid] or XXI [the Children's Health Insurance Program] (or a waiver of such a plan)."
- Covered Recipient:
  - "Physicians" and teaching hospitals
  - Does not include employees of an applicable manufacturer
- Payment or Other Transfer of Value
  - A transfer of anything of value, unless excluded
  - Transfers of value do not include a transfer that is made indirectly to a covered recipient through a third party where the manufacturer is unaware of the identity of the covered recipient

Transparency Reports Must Include:

- Name of covered recipient
- Business address of covered recipient and, if a physician, the specialty and NPI number
- The amount of the payment or other transfer of value
- The dates of the payment or other transfer of value
- A description of the form of the payment or transfer, indicated as: (a) cash or cash equivalent; (b) in-kind items or services; (c) stock, stock option, or ownership interest, dividend, profit, or other return on investment; or (d) other (as defined by HHS)
- If payment is related to a particular drug, device or medical supply, report must identify the drug, device, or supply
- A description of the payment or transfer
- Any other categories of information regarding the payment or other transfer of value HHS determines appropriate

Exclusions From Reporting

- Any transfers of value less than $10, unless the aggregate transfer of value to the covered recipient exceeds $100 during the calendar year (not taking into account items below)
- Product samples not intended to be sold and intended for patient use
- Educational materials that directly benefit patients or are intended for patient use
- Trial loan (not more than 90 days) of a covered device to permit evaluation by the covered recipient
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device
- Transfer to a physician where physician is a patient and not acting in the professional capacity of a covered recipient
- Discounts (including rebates)
- In-kind items for the provision of charity care
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund
- For covered recipients who are licensed non-medical professionals, transfers solely for non-medical professional services
- Payments solely for the services of the covered recipient with respect to expert or other services in connection with litigation matters
- If the applicable manufacturer self-insures for healthcare, payments for the provision of healthcare to employees under the plan

Physician Ownership Reporting

- Any applicable manufacturer or GPO must report the following information regarding any ownership or investment interest held by a physician (or an immediate family member) in the applicable manufacturer or GPO during the preceding year
  - The dollar amount invested by any physician
  - The “value and terms” of each such investment
  - For any payment or other transfer of value provided to a physician holding such an investment interest, all the information listed in the prior slides
  - Any other information the Secretary determines appropriate
- Exception: No reporting obligations for ownership or investment interest in a "publicly traded security" or mutual fund

Government Disclosure of Reports

- Reporting of transfers under an R&D agreement or clinical investigation regarding a new product is delayed until after the earlier of
  - FDA approval / clearance or
  - Four calendar years after the date of payment
- Information available on a public website by 2013
- Website will
  - Identify manufacturers and recipients
  - List values of transfers, nature of transfers, and any other information the Secretary determines would be helpful to the average consumer
- Manufacturers and recipients can review and submit corrections for at least 45 days prior to information being made public

Drug Sample Reporting

- Each manufacturer and authorized distributor of record must report
  - The identity and quantity of drug samples requested and distributed in a year, aggregated by name, address, professional designation and signature of practitioner and **any other category of information determined appropriate by the Secretary**
  - Reporting will be required for samples distributed by mail or common carrier, or otherwise
- Drug = prescription drug for which payment is made under Medicare, Medicaid, or CHIP
- Manufacturers should already have access to this information by virtue of PDMA compliance (if HHS does not add non-PDMA required information to the Section 6004 reports)

Limited Preemption

- "Relation to State Laws.—
  - (A) In General.– [**Effective on January 1, 2012,]** subject to subparagraph (B), the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer…to disclose or report, in any format, **the type of information** … regarding such payment or other transfer of value.
  - "(B) No Preemption of Additional Requirements.—
    - Subparagraph (A) shall not preempt any law or regulation of a State . . . that requires the disclosure or reporting of information (i) not of the type required to be disclosed or reported under this section; (ii) [excluded from the definition of payments or other transfers of value (except for the de minimis exclusion)]; (iii) by any person or entity other than an applicable manufacturer or a covered recipient; or (iv) to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes

Limited Preemption (cont'd.)

- States can require disclosures of information if the information is:
  - Not "of the type" required to be disclosed under PPACA,
  - Excluded from PPACA's reporting requirements (with an exception noted below), or
  - Regarding a payment by someone other than an applicable manufacturer and/or to someone other than a covered recipient
- Exception: 6002 "shall not preempt any [State law] . . . that requires the disclosure or reporting of information" excluded from Section 6002 Transparency Reports, "except in the case of information described in" 6002's de minimis reporting exclusion
- State gift bans would not be preempted

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- Drug = prescription drug for which payment is made under Medicare, Medicaid, or CHIP.
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THE NEW BIOSIMILARS FRAMEWORK

Implementation of the Biosimilars Framework

- FDA Organization
  - Biosimilar applications will be reviewed by the Division responsible for review and approval of the reference product
  - Biosimilars Review Committee (BRC) "will serve in an advisory capacity to the OND review divisions as they consider sponsor requests for advice about how to develop a biosimilar product and as they review biosimilar BLAs"
    - Will include experts from many disciplines and offices across CDER, representatives from CBER, and representatives from the Office of Chief Counsel
    - John Jenkins, Director of Office of New Drugs, will chair the BRC.
  - New Position – Associate Director for Biosimilars (Leah Christl, Acting)

Guidance Documents

- FDA may issue general or specific guidance, after opportunity for public comment
- The issuance or non-issuance of such guidance does not preclude approval of a biosimilar
- FDA must establish a process through which the public can provide FDA with input regarding priorities for issuing guidance

Guidance Documents (cont'd.)

- Class-specific guidance must include:
  - A description of the criteria that FDA will use to determine whether a biological product is highly similar to a reference product in such product class, and
  - The criteria, if available, that FDA will use to determine whether a biological product is interchangeable with the reference product.
  - FDA may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class, does not allow approval of a biosimilar product. FDA may, however, issue a subsequent guidance document to modify or reverse that prior position.

Definitions: Reference Product

- **Reference Product:** single biological product licensed under subsection (a) of Section 351 of the PHSA against which a biosimilar or interchangeable biological product is evaluated
- Application must contain information to show that the new product and reference product are biosimilar or interchangeable

Relationship to Reference Product and Determination of Biosimilarity

- Biological product and reference product must utilize the same mechanism or mechanisms of action for condition(s) of use prescribed, recommended, or suggested in the proposed labeling
- Condition(s) of use prescribed, recommended, or suggested in the labeling proposed for the biosimilar product must have been previously approved for the reference product
- Route of administration, dosage form, and strength of the biological product are the same as those of the reference product

What is Biosimilarity?

"The term 'biosimilar' or 'biosimilarity', in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is *highly similar* to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are *no clinically meaningful* differences between the biological product and the reference product in terms of the safety, purity, and potency of the product."

Interchangeability

- "…the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."

- "….can be expected to produce the *same clinical result as the reference product in any given patient*; and….for a biological product that is administered more than once to an individual, *the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch*."

"BioBetters"?

- Could the new biosimilars process be used to develop a "biobetter" product, or will the full BLA route be the preferred pathway? Or a hybrid?

Data Requirements

- Analytical studies demonstrating that the biosimilar product is highly similar to the reference product notwithstanding minor differences in clinically inactive components
- Animal studies, including an assessment of toxicity
- Clinical study or studies, including but not limited to the assessment of immunogenicity and pharmacokinetics or pharmacodynamics, sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biosimilar product
- *FDA may determine that one or more of these requirements are unnecessary*

Additional Information

- Must include publicly-available information regarding FDA's previous determination that the reference product is safe, pure, and potent
- May include:
  - Any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product
  - Information demonstrating that the biological product is interchangeable with the reference product

REMS

- The authority of FDA with respect to risk evaluation and mitigation strategies (REMS) under the FDCA applies to biosimilar or interchangeable products in the same manner it applies to reference products

Manufacturing

- Facility in which the biosimilar product is manufactured, processed, packed, or held must meet standards designed to assure that the product continues to be safe pure, and potent

Payment for Biosimilars

- Payment for a biosimilar product is based on the average sales price (ASP) (or a volume weighted ASP of all the product's national drug codes if it has more than one), plus 6 percent of the ASP of the reference product as calculated for a single source biologic product.

- The reference biologic continues to be paid at 106 percent of its own ASP.

Transitioning Certain Products From FDCA to PHSA

- There is a 10-year period after enactment of the new provisions during which any NDA for a product meeting the biologic definition may be submitted under the FDCA so long as another biological product in its product class has been the subject of an FDCA approval prior to enactment.
- 10 years after enactment, any biological product approved under an NDA will be deemed to have been approved under PHSA §351.

User Fees

- Beginning October 2010, will develop recommendations to submit to Congress for user fees for biosimilar applications.
  - In developing recommendations, FDA must consult with industry, health care professionals, scientific experts, and other stakeholders and entities.
- Coincides with the next user fee negotiation cycle in 2012

Biosimilars: Innovator Exclusivities

- 12 years data exclusivity where no biosimilar may be approved - first 4 years where no biosimilar application may be submitted
- Potential orphan exclusivity for longer of 7 years from designation or 12 year data exclusivity
- Additional 6 months for pediatric studies

No "Evergreening"

"FIRST LICENSURE.— [the 12-year exclusivity and 4-year biosimilar application delay] shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

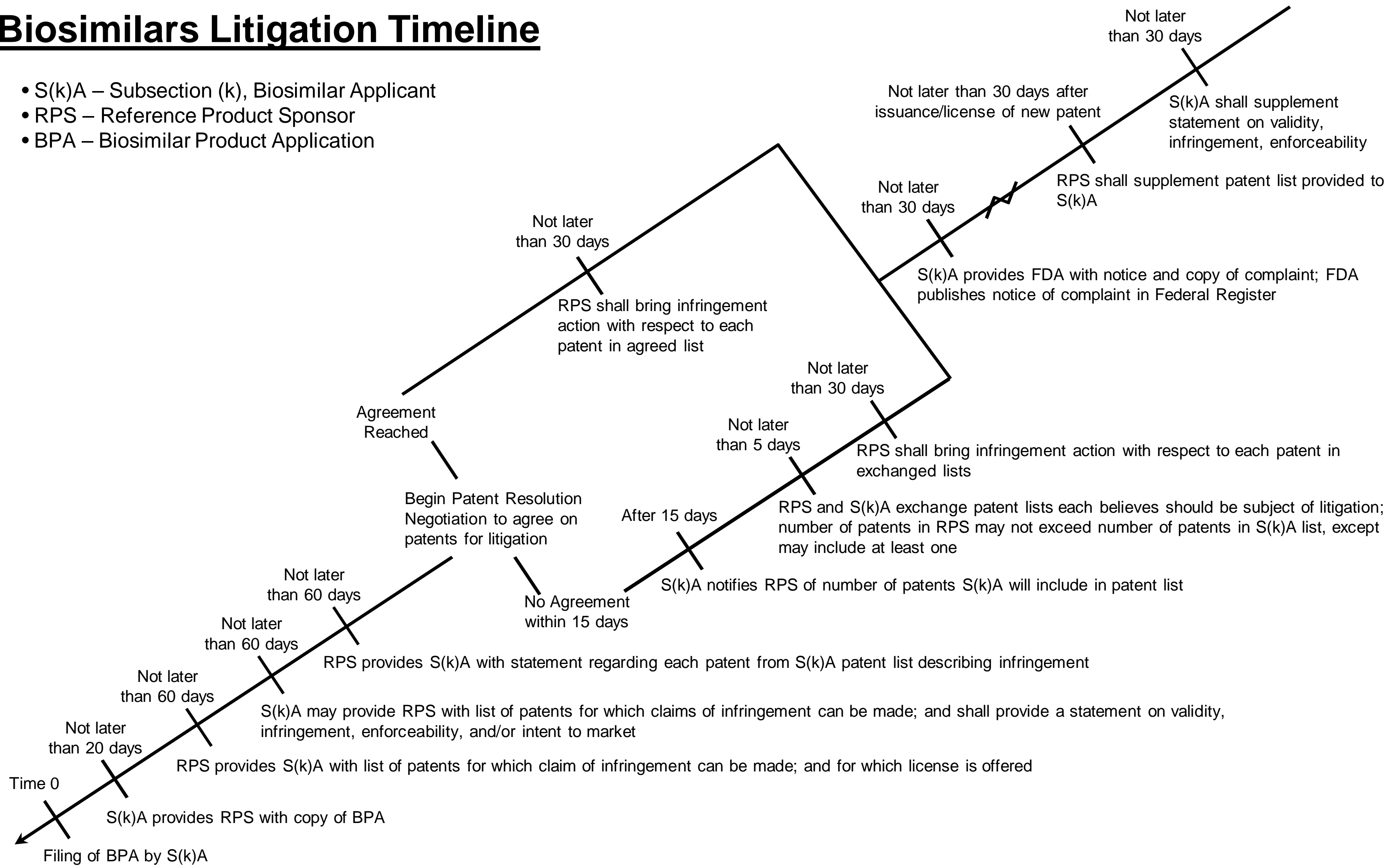
> (I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or
>
> (II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency."

Interchangeable Product Exclusivity

- Only products deemed interchangeable (as opposed to biosimilar) are eligible for exclusivity
- FDA may not approve a second interchangeable product until the earlier of:
  - 1 year after commercial marketing of first interchangeable product
  - 18 months after final court decision or dismissal in patent suit under patent notice provisions
  - 42 months after approval of first interchangeable if sued for patent infringement under patent notice provisions and still ongoing after 42 months
  - 18 months after approval of first interchangeable if not sued under patent notice provisions

Biosimilars Litigation Timeline

- S(k)A – Subsection (k), Biosimilar Applicant
- RPS – Reference Product Sponsor
- BPA – Biosimilar Product Application



Patent Procedures

- Within 20 days of receipt for review of Biosimilar Application by FDA, biosimilar applicant must send copy of application to innovator
- Within 60 days of receipt of biosimilar application, innovator must send biosimilar applicant a listing of patents believed to be infringed if biosimilar marketed, and any offers to license
- Within 60 days of receipt of patent list, biosimilar applicant must provide a notice of patent certification regarding non-marketing, non-infringement, invalidity and/or unenforceability
- Within 60 days of receipt of patent certification, innovator must respond with counter position and response regarding infringement, validity, and/or enforceability
- After exchange of statements, parties shall engage in good faith negotiations to agree on list of patents to be asserted

Patent Procedures

- If within 15 days of start of negotiations, parties do not agree on the list of patents, the parties will exchange lists of patents each believes should be asserted
  - the biosimilar applicant will first notify the innovator of the number of patents they will list, and then the patents lists will be simultaneously exchanged within 5 days
  - the innovator's list may not be longer than the biosimilar applicant's list, unless the biosimilar applicant does not list any, in which case the innovator may list 1 patent
- After 15 days:
  - if no agreement: innovator must file suit within 30 days of exchange of patent lists for all listed patents
  - if agreement: within 30 days of agreement on asserted patents, innovator must file suit

Limitations on Innovator Review

- Biosimilar applicant provides application information to:
  - One or more outside attorneys
  - One in-house attorney
  - Patent owner representative if they retained right to assert

- "provided that . . . they do not engage, formally or informally, in patent prosecution relevant or related to the referenced product"

- Others, including scientific consultants, require written agreement

Sanctions for Non-compliance

- If patent is included on list, but suit is not timely filed:
  - New 35 USC 271(e)(2)(C) limits innovator to reasonable royalty where suit was filed after 30-day period; or if dismissed without prejudice during 30-day period

- If patent is omitted from list? THE NUCLEAR OPTION
  - New 35 USC 271(e)(6)(C) renders such omitted patents UNENFORCEABLE:

    The owner of a patent that should have been included in the list . . . but was not timely included in such list may not bring an action under this section for infringement of the patent with respect to the biological product."

Strategic Issues and Potential Pitfalls

- No Orange Book Listing:
  - Exchange of information required to identify relevant patents
  - Draconian consequences for failure to disclose patents
- What patents are relevant?
  - Drug targets, therapeutic compounds, formulations, methods of manufacture, methods of use, cell lines, starting materials
  - Research tools?
- Third Party Patents
  - Third party patent owner participation is required
  - Significant impact on their rights

Planning and Preparation for FOBs

- Identify and continuously update list of all relevant patents for each product in development
  - Determine expiration dates and prioritize
- Review applicable patent licenses
  - Do you have first pass enforcement rights? How much third party participation / cooperation is required? What are your notification obligations and corresponding response timelines?
  - Renegotiate license if necessary to streamline process for selecting and enforcing key patents
- Select appropriate in-house and outside personnel
  - Who will analyze and review confidential FOB application

Questions?

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