FOUR PROPOSALS TO ENHANCE GENERIC COMPETITION

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Crucial Topic

- Important exercise: brand innovation gets attention; generic access often does not
- I have comprehensively studied issue:
  - Co-author of leading IP/antitrust treatise
  - Author of more than 90 articles (40 on pharmaceutical antitrust law)
  - Author of amicus curiae briefs on behalf of hundreds of professors
  - Frequently cited in media (1000+ times) and courts (including U.S. Supreme Court)

Balance Tilts Away from Generic Access, Part 1

- Hatch-Waxman's *180-day exclusivity* has morphed from incentive to challenge patents to tool for brand firms to pay first-filing generics to delay entering market
- *REMS patents* can be used to block generic competition
  - Orange Book listing could allow brand to obtain 30-month stay (even though REMS patents are nonlistable method of product distribution rather than listable "drug" or "method of using the drug")
  - Not needed for innovation: Many REMS patents were issued before *Alice* decision restricting patentable subject matter and do not appear necessary to recover significant investment
    - More than 60 NDAs with REMS but REMS patents listed in Orange Book for only 5
    - *See* Michael A. Carrier, Carl J. Minniti III, & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, Boston University Law Review at 139-40 (forthcoming 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2995827
  - Example of harm: Jazz Pharmaceuticals argued against Xyrem SSRS waiver for generics utilizing multiple pharmacies with several of its REMS patents requiring "central pharmacy"

Balance Tilts Away from Generic Access, Part 2

- Some *reformulations* cannibalize profitable drugs, making no economic sense other than by stifling generic entry
  - *See* Michael A. Carrier & Steve Shadowen, *Product Hopping: A New Framework*, 92 Notre Dame Law Review 167 (2016), https://papers.ssrn.com/sol3/Papers.cfm?abstract_id=2747526
  - *Citizen petitions* used to delay generic entry, with my empirical study showing FDA denies 92% of 505(q) petitions, 98% of late-filed petitions (within 6 months of expiration of patent or FDA exclusivity), and 100% of simultaneous petitions (when FDA resolves petition on same day it approves generic)
  - *See* Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 American University Law Review 305 (2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2832319
    - Concerning examples: Shire ViroPharma's 46 regulatory/court filings, Teva's multiple Copaxone petitions, Bayer's Mirena petition one day before patent expiration, Mylan's delayed filing of petition on EpiPen alternative until expiration of settlement with generic
    - *See* Carrier & Minniti, *Citizen Petitions*, at 344-47; Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 Cornell Law Review Online 53, 64-66 (2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2841445

Proposal 1: Clarify Orange Book Listing

- FDA should provide unequivocal guidance that REMS patents not listable in Orange Book
  - Amendment could be incorporated into final sentence of 21 C.F.R.§ 314.53(b)(1) as follows:
  - “Process patents, patents claiming packaging, patents claiming metabolites, ~~**and**~~ patents claiming intermediates**, and patents claiming FDA-approved Risk Evaluation and Mitigation Strategies (REMS) required under 21 U.S.C. section 355-(1)(a)(1)** are not covered by this section, and information on these patents must not be submitted to FDA.”

Proposal 2: Expedite SSRS Negotiations

- Given delay from slow-walking negotiations (e.g., Suboxone, Xyrem -- *see* Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, Cornell Law Review, at 37-42 (forthcoming 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2979565)…
  - FDA should more quickly allow waiver
  - FDA could discuss expectations during kickoff meeting, which could form basis for more rapid waivers based on violations of industry norms
  - FDA could develop guidance based on its experience of when "burden [] outweigh[s] benefit" considering factors such as
    - (a) number of ANDA applicants
    - (b) complexity of ETASU restrictions
    - (c) potential delay in generic approval
    - (d) history of successful or unsuccessful brand/generic negotiations
  - FDA could consider benefits from using templates in SSRS submission
    - Sponsors required to specify terms would accept by providing governance terms, NDAs, patent/ trade secret licenses, provisions for diligence information, indemnity and insurance provisions
  - Agency should consider setting time frame (like CREATES Act's 120-day period) within which negotiation must be concluded

Proposal 3: Loosen distribution-restriction bottleneck, Part 1

- Even though FDAAA *states that brands shall not use REMS to "block or delay" generics*, sample denials and REMS patents can do so, which leads to recommended statutory changes that FDA could advocate that would effectuate Congress's objectives:
  - 21 U.S.C. § 355-1(f)(8): "No holder of an approved covered application shall use any element to assure safe use, **whether patented or not**, required by the Secretary under this subsection to block or delay approval . . . ."
  - 21 U.S.C. § 355-1(i)(1)(B)(ii): "[A]n aspect of the elements to assure safe use for the applicable listed drug ~~is claimed by a patent that has not expired or~~ is a method or process that, as a trade secret, is entitled to protection, and the applicant for the abbreviated new drug application certifies that it has sought a license for use of an aspect of the elements to assure safe use for the applicable listed drug and that it was unable to obtain a license."
  - "A certification under clause (ii) shall include a description of the efforts made by the applicant for the abbreviated new drug application to obtain a license. In a case described in clause (ii), the Secretary may seek to negotiate a voluntary agreement with the owner of the **trade secret, ~~patent, method, or process for a license~~** under which the applicant for such abbreviated new drug application may use an aspect of the elements to assure safe use, if required under subsection (f) for the applicable listed drug, that is **~~claimed by a patent that has not expired or is~~ protected by** a method or process that as a trade secret is entitled to protection."

Proposal 3: Loosen distribution-restriction bottleneck, Part 2

- FDA also could recommend that Congress adopt amendment like Section 14 of America Invents Act, which deems tax-strategy patents to fall within prior art and thus be invalid. Potential amendment:
  - "**Any method or system approved by the FDA as a component of a risk evaluation and mitigation strategy, whether known or unknown at the time of the invention or application for patent, shall be deemed insufficient to differentiate a claimed invention from the prior art.**"

Proposal 4: Address Harms from Citizen Petitions

- FDA should include comprehensive list of 505(q) petitions in annual reports to Congress. In addition to currently required categories, list should include:
  - Timing of petition in relation to patents listed in Orange Book,
  - Time FDA expended on petition,
  - Delay (if any) in generic approval caused by petition and determination of how delay calculated
- FDA should use power to summarily dispose of petitions under section 505(q)(1)(E)
- When FDA approves ANDA and resolves 505(q) petition in same month (or at least on same day), should determine whether (1) ANDA approval was delayed as result of FDA decision on petition or (2) FDA's announcement of its decision was delayed until ANDA approval
- FDA should determine how much money and time incurred resolving 505(q) petitions
- FDA should explore whether section 505 allows it to require petitioners to certify that objections filed within reasonable time of discovering claim
  - E.g., Mylan filed petition challenging Teva's EpiPen alternative at least *5 years* after most likely was aware of ANDA product specifications. (*See* Carrier & Minniti, *Untold EpiPen Story*, at 650)