

The logo for Duane Morris, featuring the name in a white serif font on a dark blue rectangular background. The background of the slide is a light green with a subtle wave pattern and a horizontal dotted line.

The Biosimilars Patent Dance

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The Patent Dance under the BPCIA (42 U.S.C. § 262(I))



INFRINGING ACT

BPCIA

Submission of the biosimilar application

- For owned or exclusively licensed patents identified by the RPS (if the patent dance takes place); or
- Patents that “could be” identified by RPS if the biosimilar fails to provide the application and manufacturing information to the BLA holder.

35 USC § 271(e)(2)(C)

PROCEDURES AFTER BIOSIMILAR APPLICATION ACCEPTED

20 days after acceptance Applicant provides **application and Mfg. info** to RPS

60 days: RPS provides list of owned or exclusively licensed patents and patents for license

60 days: Applicant provides patent list, **factual & legal bases** & response re: **license**

60 days, RPS provides basis for infringement & response to validity and enforceability bases



PATENT NEGOTIATION/LITIGATION

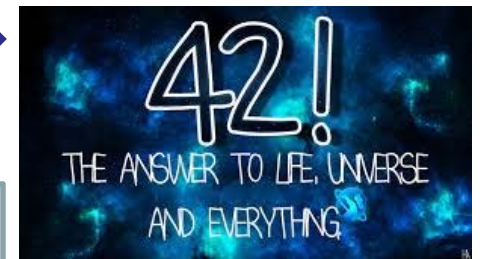
15 days Negotiation: If agree to patent list, RPS has **30 days** to sue (for all patents agreed to)

15 days: If no agreement, Applicant provides # of patents it will list (controls # in suit)

5 days: Simultaneous exchange of patents

30 days: RPS to sue on all exchanged patents

Pop up Dance



**BE THERE
OR BE** 

LIMITS ON LITIGATION

- NO stay of approval
- If Applicant starts the dance, neither party can bring DJ until Applicant provides 180-day notice of marketing (then RPS can seek PI for patents identified but not on the final list)
- If Applicant steps out of the dance, RPS can bring DJ action for any patent in RPS first or pop-up list.
- If Applicant never starts the dance, RPS can file DJ only on product & use claims.

Vicki Norton is Co-Leader of the Global Life Sciences Group at Duane Morris, LLP, where she practices in the area of intellectual property law with a focus on biopharma, pharma, and diagnostics patent counseling and litigation. She also advises clients on worldwide patent strategy, including identifying patent coverage issues, auditing technology portfolios to assist clients in transactions and venture opportunities and formulating strategic objectives for prosecution. Dr. Norton has also advised clients on all facets of litigation involving technologies including biologic drugs, transformed CHO cells, transgenic plants, small molecule drugs and nanotechnology. Prior to attending law school, Vicki served as a research and teaching assistant at UC Davis, where she studied histone acetylation and chromatin structure for her doctoral research. Dr. Norton is a 1994 graduate of UCLA Law School, where she was a managing editor of the UCLA Law Review and Order of the Coif. Vicki also serves on the Board of NanoTecNexus, a non-profit organization which promotes nanoscience STEM education.

A business card for Vicki G. Norton, Ph.D., Partner at Duane Morris LLP. The card features the Duane Morris logo at the top left, the website www.duanemorris.com, and contact information including phone, fax, and email details. It also includes links for E-MAIL, BIO, and VCARD.

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