



MARCH 13, 2013



It's Not Just Boilerplate!

Best practices for drafting collaboration agreements to protect your IP

By Elizabeth A. Howard, Ph.D. & Michael C. Spillner

Presenters



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- J.D., Hastings College of the Law
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Outline



1. The collaboration conundrum
2. The Tekmira case: a cautionary tale
3. Best practices for drafting specific provisions

- 1. The collaboration conundrum**
2. The Tekmira case: a cautionary tale
3. Best practices for drafting specific provisions



The collaboration conundrum



Collaborations are for the parties' mutual benefit,
but their interests are never fully aligned.

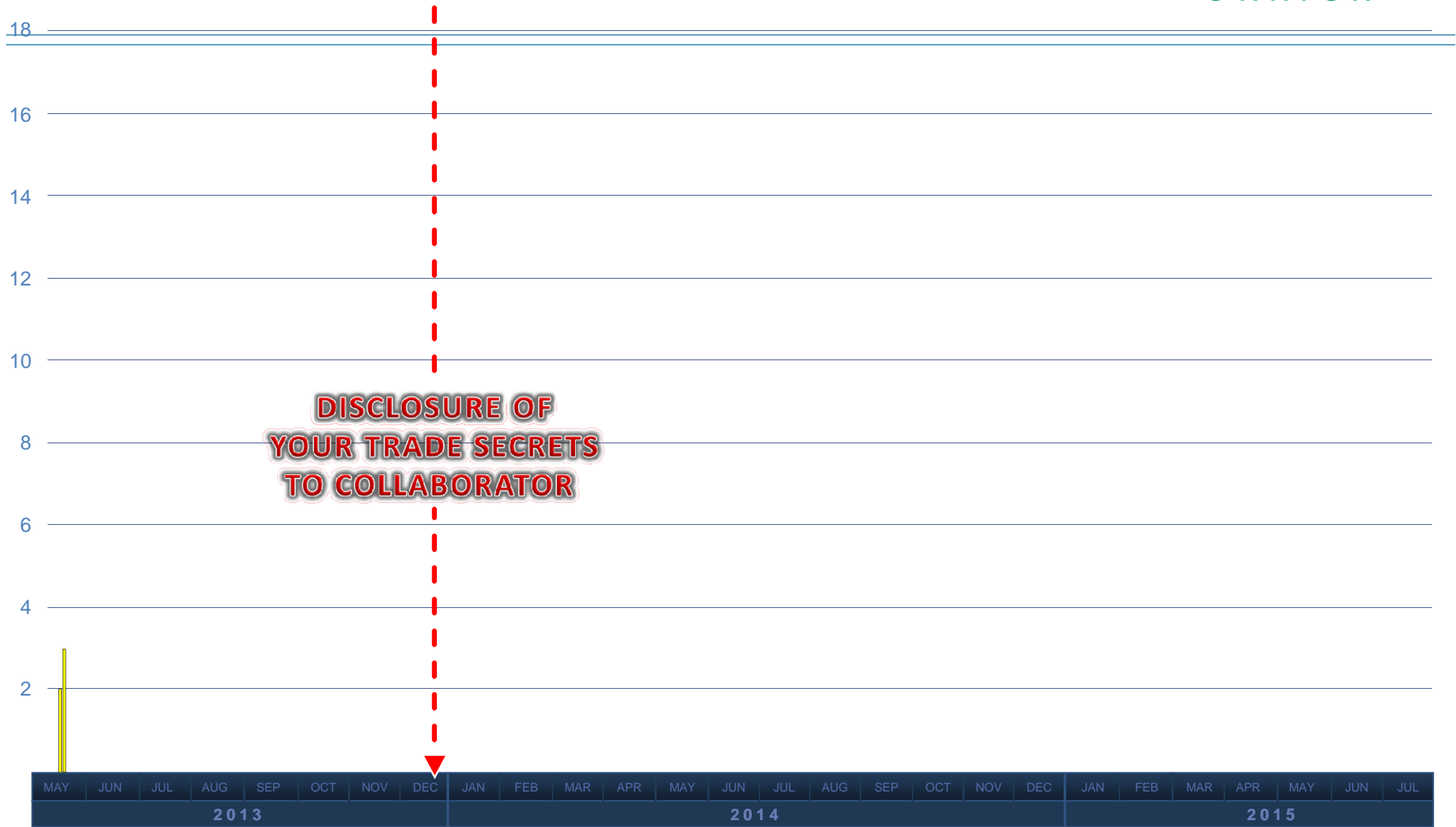


The collaboration conundrum

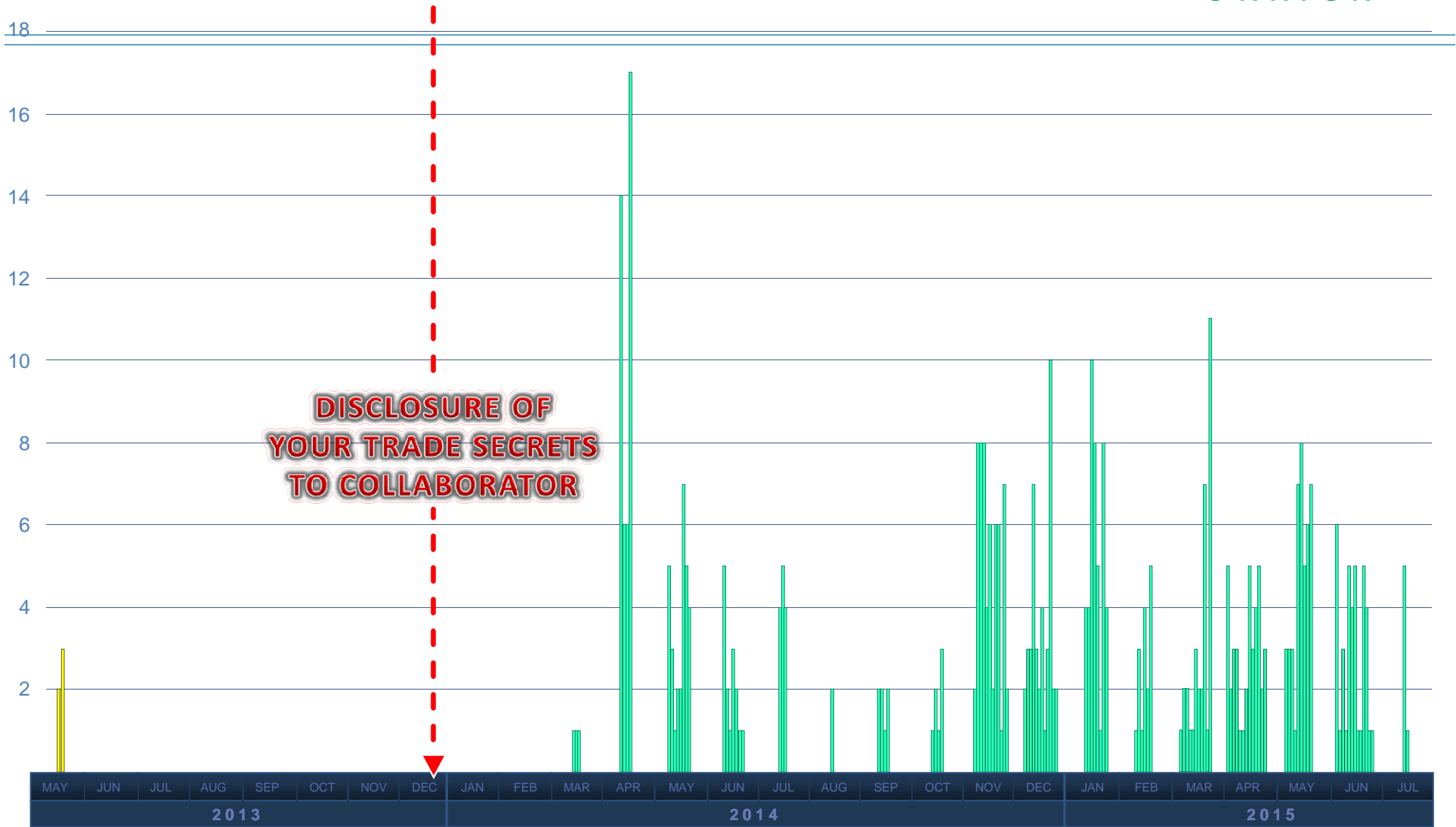


A collaborator today can be a competitor tomorrow.

The risk



The risk



Strategies to deal with the conundrum



- rock the boat
- achieve clarity
- limit access
- don't share what you can't afford to lose

Outline



1. The collaboration conundrum
- 2. The Tekmira case: a cautionary tale**
3. Best practices for drafting specific provisions

The Tekmira case: a cautionary tale



- drug development collaboration
- collaborators became competitors
- lawsuit over IP ownership

Outline



1. The collaboration conundrum
2. The Tekmira case: a cautionary tale
- 3. Best practices for drafting specific provisions**

Best practices for specific provisions



- confidentiality clauses
- IP clauses
- license and sublicense rights

Best practices for specific provisions



- **confidentiality clauses**
- IP clauses
- license and sublicense rights

Confidentiality clauses



VII, the same principles governing control of the resolution of the dispute, consent to settlements of the dispute, and implementation of the settlement of the dispute will apply.

7.10 Interpretation of Patent Judgments. If any claim relating to a patent under the ALNYLAM Patent Rights or the PROTIVA Patent Rights or Joint Patent Rights becomes the subject of a judgment, decree or decision of a court, tribunal, or other authority of competent jurisdiction in any country, which judgment, decree, or decision is or becomes final (there being no further right of review) and adjudicates the validity, enforceability, scope, or infringement of

8.1 Non-Use and Non-Disclosure of Confidential Information. Each Party agrees that all Confidential Information of a Party that is disclosed by a Party to the other Party (a) will not be used by the receiving Party except in connection with the activities contemplated by this Agreement or in order to further the purposes of this Agreement, (b) will be maintained in confidence by the receiving Party,

Territory (including payment of costs associated therewith). PROTIVA shall assume full responsibility, at its sole cost and expense, for any infringement of a trademark for a PROTIVA Development Product by a Third Party and for any claims of infringement of the rights of a Third Party by the use of a trademark in connection with such PROTIVA Development Product.

7.12 Patent Certification. To the extent required by law or permitted by law, the Parties shall use reasonable efforts to maintain with the applicable regulatory authorities during the Term correct and complete listings of applicable patent rights for ALNYLAM Development Products and PROTIVA Development Products, as the case may be, being commercialized, including all so called "Orange Book" listings required under the Hatch-Waxman Act.

ARTICLE VIII – CONFIDENTIAL INFORMATION, PUBLICATION, AND NON-SOLICITATION

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Confidentiality clauses: non-use



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Confidentiality clauses: non-disclosure



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Confidentiality clauses: exceptions



Exceptions – they can swallow the rule.

consent of the disclosing Party. **Notwithstanding the foregoing,** the receiving Party will be entitled to use and disclose Confidential Information of the disclosing Party which (i) was known by the receiving Party or its Affiliates prior to its date of disclosure by the disclosing Party to the receiving Party as demonstrated by legally admissible evidence available to the receiving Party or its Affiliates, (ii) either before or after the date of the disclosure such Confidential Information is lawfully disclosed to the receiving Party or its Affiliates by sources other than the disclosing Party, (iii) either before or after the date of the disclosure by the disclosing Party to the receiving Party such Confidential Information becomes published or otherwise part of the public domain through no fault or omission on the part of the receiving Party or its Affiliates, (iv) is independently developed by or for the receiving Party or its Affiliates without reference to or in reliance upon the Confidential Information as demonstrated by legally admissible evidence available to the receiving Party or its Affiliates, (v) is reasonably necessary to conduct clinical trials or to obtain regulatory approval of RNAi Products or miRNA Products or for the prosecution and maintenance of patent rights, (vi) is reasonably required in order for a Party to obtain financing or conduct discussions with Development or Commercialization partners so long as such Third Party recipients are bound by an obligation of confidentiality or (vii) in the reasonable judgment of the disclosing Party is required to be disclosed by the receiving Party to comply with applicable laws or regulations or legal process, including without limitation by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or NASDAQ, provided that the receiving Party provides prior written notice of such disclosure to the disclosing Party and takes reasonable and lawful actions to avoid or minimize the extent of such disclosure.

Standard exceptions



- known by receiving party prior to effective date
- lawfully disclosed to receiving party by another
- the information becomes published through no fault of the receiving party
- independently developed by receiving party without reference to the confidential information

Non-standard exceptions



information can be disclosed if “reasonably necessary” to conduct clinical trials or obtain regulatory approval

Non-standard exceptions



information can be disclosed if “reasonably necessary” for the prosecution or maintenance of patent rights

Non-standard exceptions



information can be disclosed if “reasonably required” for a party to obtain financing or conduct discussions with development or commercialization partners, so long as such third party recipients are bound by an obligation of confidentiality

Non-standard exceptions



information can be disclosed if “reasonably required” for a party **to obtain financing or conduct discussions with development or commercialization partners**, so long as such third party recipients are bound by an obligation of confidentiality

Non-standard exceptions



information can be disclosed if “reasonably required” for a party **to obtain financing or conduct discussions with development or commercialization partners**, so long as such third party recipients are bound by an obligation of confidentiality

- *or:* “You must keep my information confidential unless you can sell it.”

Non-standard exceptions



information can be disclosed if “reasonably required” for a party to obtain financing or conduct discussions with development or commercialization partners, **so long as such third party recipients are bound by an obligation of confidentiality**

Non-standard exceptions



information can be disclosed if “reasonably required” to comply with applicable laws or regulations or legal process

Notice and consent



consent of the disclosing Party. **Notwithstanding the foregoing,** the receiving Party will be entitled to use and disclose Confidential Information of the disclosing Party which (i) was known by the receiving Party or its Affiliates prior to its date of disclosure by the disclosing Party to the receiving Party as demonstrated by legally admissible evidence available to the receiving Party or its Affiliates, (ii) either before or after the date of the disclosure such Confidential Information is lawfully disclosed to the receiving Party or its Affiliates by sources other than the disclosing Party, (iii) either before or after the date of the disclosure by the disclosing Party to the receiving Party such Confidential Information becomes published or otherwise part of the public domain through no fault or omission on the part of the receiving Party or its Affiliates, (iv) is independently developed by or for the receiving Party or its Affiliates without reference to or in reliance upon the Confidential Information as demonstrated by legally admissible evidence available to the receiving Party or its Affiliates, (v) is reasonably necessary to conduct clinical trials or to obtain regulatory approval of RNAi Products or miRNA Products or for the prosecution and maintenance of patent rights, (vi) is reasonably required in order for a Party to obtain financing or conduct discussions with Development or Commercialization partners so long as such Third Party recipients are bound by an obligation of confidentiality or (vii) in the reasonable judgment of the disclosing Party is required to be disclosed by the receiving Party to comply with applicable laws or regulations or legal process, including without limitation by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or NASDAQ, **provided that the receiving Party provides prior written notice of such disclosure to the disclosing Party and takes reasonable and lawful actions to avoid or minimize the extent of such disclosure.**

Limitations on disclosures



consent of the disclosing Party. Notwithstanding the foregoing, the receiving Party will be entitled to use and disclose Confidential Information of the disclosing Party which (i) was known by the receiving Party or its Affiliates prior to its date of disclosure by the disclosing Party to the receiving Party as demonstrated by legally admissible evidence available to the receiving Party or its Affiliates, (ii) either before or after the date of the disclosure such Confidential Information is lawfully disclosed to the receiving Party or its Affiliates by sources other than the disclosing Party, (iii) either before or after the date of the disclosure by the disclosing Party to the receiving Party such Confidential Information becomes published or otherwise part of the public domain through no fault or omission on the part of the receiving Party or its Affiliates, (iv) is

independently developed, or (v) is obtained by the receiving Party or its Affiliates through no fault or omission on the part of the receiving Party or its Affiliates. The disclosing Party is liable for any breach of the non-disclosure obligation of its consultants, advisors, Affiliates and Sublicensees as applicable.

Information of the disclosing Party. The disclosing Party is liable for any breach of the non-disclosure obligation of its consultants, advisors, Affiliates and Sublicensees as applicable.

8.3 **Publication.** PROTIVA and ALNYLAM each acknowledge the other Party's interest in publishing the results of the R&D Research Plan and the PLK Research Plan. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to Section 8.1 and 8.2, either Party, its Affiliates, or their respective employees or consultants wishing to make a publication or a disclosure to a Third Party relating to the R&D

8.2 Limitation on Disclosures. Each Party agrees that it will provide Confidential Information received from the other Party solely to its employees, consultants and advisors, and the employees, consultants and advisors of its Affiliates or Sublicensees as applicable, who have a legitimate business need to know and an obligation to maintain in confidence the Confidential Information of the disclosing Party. The disclosing Party is liable for any breach of the non-disclosure obligation of its consultants, advisors, Affiliates and Sublicensees as applicable.

If a Party discloses Confidential Information to the other Party or its Affiliates, the disclosing Party shall be deemed to have disclosed such Confidential Information to the other Party and its Affiliates, including without limitation, its employees, consultants and advisors, and the employees, consultants and advisors of its Affiliates or Sublicensees as applicable, who have a legitimate business need to know and an obligation to maintain in confidence the Confidential Information of the disclosing Party. The disclosing Party is liable for any breach of the non-disclosure obligation of its consultants, advisors, Affiliates and Sublicensees as applicable.

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or disclosure.

8.4 **Non-Solicitation.** Until January 8, 2012, neither ALNYLAM nor any of its Affiliates will knowingly offer to hire or hire any individual who is, at such time, an officer or employee of PROTIVA or any of its Affiliates, and who was, at any time in the preceding three (3) months, involved in (i) selecting the PROTIVA Development Targets, (ii) the Development and Commercialization of PROTIVA Development Products and/or (iii) conducting the R&D Research Plan or Second Target Research Plan or PLK Research Plan. For clarity, placing an advertisement in a newspaper, periodical or other publication of general availability, or other general recruitment activities not directed at a particular individual, do not constitute an "offer to hire."

ARTICLE IX – REPORTS, TAXES AND PAYMENTS

9.1 **Terminology.** For purposes of Articles II and III, the "Licensee" referred to in this Article IX shall be understood to be PROTIVA. For purposes of Article IV, the "Licensee" referred to in this Article IX shall be understood to be ALNYLAM.

9.2 **Reports.** As to each Royalty Quarter commencing with the Royalty Quarter

Advanced confidentiality protection



- limit disclosure to specific persons named in advance in writing
- limit disclosure to specific purpose
- require employees to personally execute NDA
- require encryption and passwords for electronic files
- require maintenance of access log and audit rights
- prohibit any disclosure to third parties
- always require advance notice & written consent

Best practices for specific provisions



- confidentiality clauses
- **IP clauses**
- license and sublicense rights

IP Clauses



example provision

ALNYLAM will solely own all intellectual property discovered and reduced to practice solely by ALNYLAM directly in the course of work conducted after the Original Effective Date under the Second Target Research Plan or under the PLK Research Plan or under the R&D Research Plan. PROTIVA will solely own all intellectual property discovered and reduced to practice solely by PROTIVA directly in the course of work conducted after the Original Effective Date under the Second Target Research Plan or under the PLK Research Plan or under the R&D Research Plan. The Parties will jointly own all intellectual property discovered and reduced to practice jointly by ALNYLAM and PROTIVA directly in the course of work conducted after the Original Effective Date under the Second Target Research Plan or under the PLK Research Plan or under the R&D Research Plan, and all Joint Patent Rights.

Preexisting IP



- ownership – keep with original owner
- how to define
- right to use / license / sublicense

Improvements / derivatives



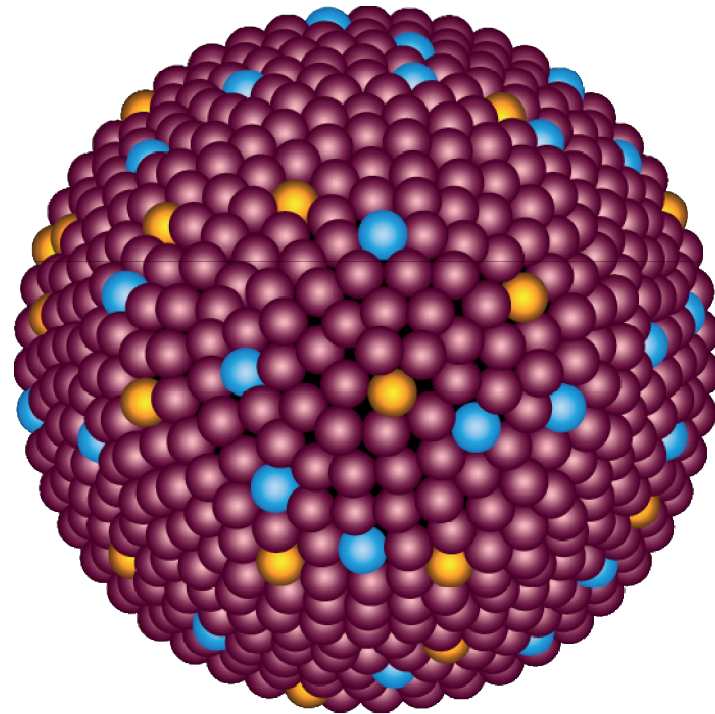
when one party uses the information it learns from the collaboration as a starting point for new inventions

Patent thicket



Your
IP

Patent thicket



Improvements / derivatives



- threshold issue of whether to allow improvements
- if you decide to allow improvements
 - specify purposes for which improvements can be made
 - address ownership
 - address ability to use, license, sublicense improvements

Collaboration IP



- defining collaboration IP
 - consider periodic updates to ensure parties are on same page
 - consider streamlined arbitration process to resolve disputes
- ownership of collaboration IP
- rights to use, license, sublicense collaboration IP

Right to patent



determined in accordance with United States patent laws for determining inventorship. ALNYLAM will solely own all intellectual property discovered and reduced to practice solely by ALNYLAM directly in the course of work conducted after the Original Effective Date under the Second Target Research Plan or under the PLK Research Plan or under the R&D Research Plan. PROTIVA will solely own all intellectual property discovered and reduced to practice solely by PROTIVA directly in the course of work conducted after the Original Effective Date under the Second Target Research Plan or under the PLK Research Plan or under the R&D Research Plan. The Parties will jointly own all intellectual property discovered and reduced to practice jointly by ALNYLAM and PROTIVA directly in the course of work conducted after the Original Effective Date under the Second Target Research Plan or under the PLK Research Plan or under the R&D Research Plan, and all Joint Patent Rights.

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7.2 Prosecution and Maintenance of Patent Rights. ALNYLAM will have the sole right and responsibility, at ALNYLAM's discretion and at its expense, to file, prosecute and maintain patent protection in the Territory for all ALNYLAM Patent Rights, except for Exclusively Licensed Tekmira IP. PROTIVA will have the sole right and responsibility, at PROTIVA's discretion and at its expense, to file, prosecute and maintain patent protection in the Territory for all PROTIVA Patent Rights.

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7.4 Cooperation. Each Party hereby agrees: (a) to make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake patent prosecution; (b) to provide the other Party with copies of all material correspondence pertaining to prosecution with the patent offices; (c) to cooperate, if necessary and appropriate, with the other Party in gaining patent term extensions wherever applicable to patent rights; and (d) to endeavor in good faith to coordinate its efforts with the other Party to minimize or avoid interference with the prosecution and maintenance of the other Party's patent applications.

7.5 Third Party Infringement of ALNYLAM Patent Rights.

(a) Each Party will promptly report in writing to the other Party during the Term any known or suspected infringement by a Third Party of any of the ALNYLAM Patent Rights of which such Party becomes aware, as such infringement relates to Research, Development or



Right to patent



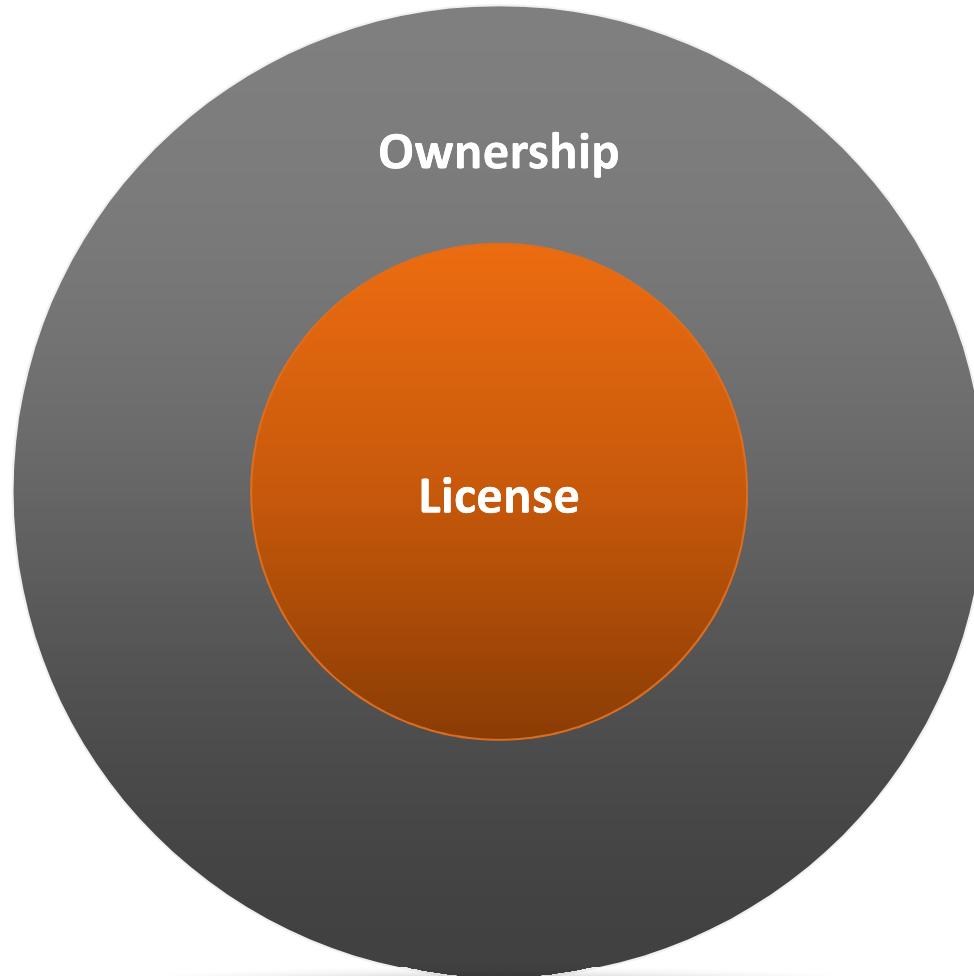
- preexisting IP
- improvements
- collaboration IP
- notice & consent

Best practices for specific provisions



- confidentiality clauses
- IP clauses
- **license and sublicense rights**

Ownership vs. licensing



License grant



clarify what is being licensed

- patents
- know-how
- other rights
- other information

License grant



clarify scope of license

- right to use, commercialize, manufacture, etc.
- for any purpose, or only purpose of collaboration?
- for any use?
- for whose benefit?

Sublicense rights



decide whether to allow sublicense rights or not

- you may lose control over your IP
- you may not be getting an appropriate benefit
- you may lose business opportunities

Sublicense rights



if you decide to grant sublicense rights

- get the appropriate benefit of any sublicense
- protect your information

Best practices



- rock the boat
- clarity and transparency
- limit access of what is shared
- don't share what you can't afford to lose

Thank you



For copies of this presentation
and MCLE forms, please visit:

<http://www.orrick.com/Events-and-Publications/Pages/It-Is-Not-Just-Boilerplate.aspx>

Thank you



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