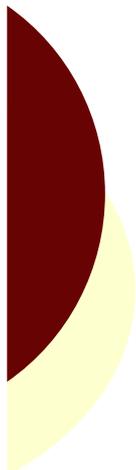


# *MANAGING PATENT LICENSE AGREEMENTS*

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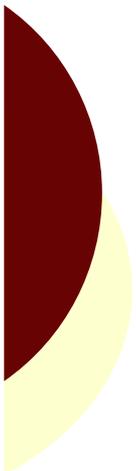
*Francisco Bernardo Noriega*  
*ABG PATENTES*



## *The Licensing process*

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- Strategic Planning
- Finding potential opportunities
- Preparatory work
- Contacting potential partners
- Securing negotiation
- Negotiating terms
- Drafting the agreement
- Management of the deal

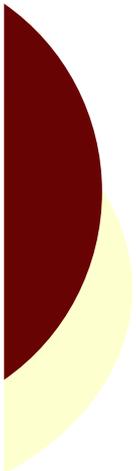
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## Why to license? Strategic planning

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- Passive form of exploitation
- Develop and market your technology
- Increase financial resources for the project
- Bring in expertise through adequate partnering
- Cultural and regulatory hurdles
- Sales: best marketing partner in each area

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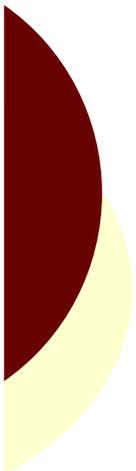
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## Before everything starts: finding potential opportunities and preparatory work

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- Competitive intelligence: know your potential licensee/licensor.
- Find the right moment: finances, competing technologies, business opportunity.
- Homework: licensee and licensor should prepare due diligence.
- Basic and confidential information package.

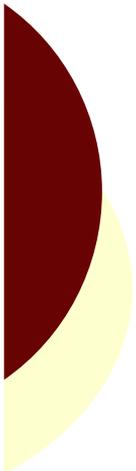
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## IP Due Diligence

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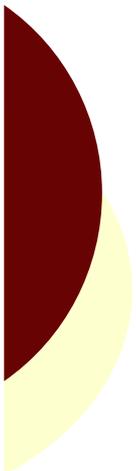
- Existing IP rights covering the technology
- Ownership, third party rights
- Freedom to operate
- Due Diligence as a negotiating tool
- Improve your position while you can

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## Securing the negotiation

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- Getting an exclusive option to a license
- Letter of understanding
- Setting the framework: time, scope
- Defining important terms of the license agreement at this stage
- Confidentiality terms

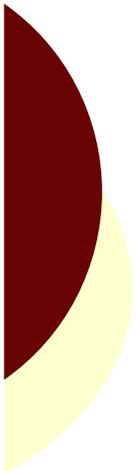
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## The Term Sheet

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- The Licensed technology
- Exclusivity and Sublicenses
- Field of use and territory
- Considerations and term
- Performance, reports, inspections and audits
- Know-how, new technology and options
- Patents: prosecution, maintenance, new patents
- Infringement and validity issues
- Warranties
- Liabilities, disputes, law applicable

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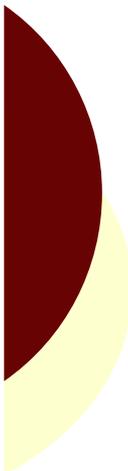
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## The Licensed Technology

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- **License:** to give someone permission to do something which would otherwise be forbidden. In the case of technology it is difficult because it is an intangible asset.
- Limited by **claims** of patents, otherwise proprietary information, trade secret or know-how.
- The **granting clause:** defining “Licensed product” or “Licensed process” with great precision. Confine licensee to what he can do best.
- Define “Licensed IP rights” or “Licensed patents”.
- License of **unpatented technology:** information, know-how.

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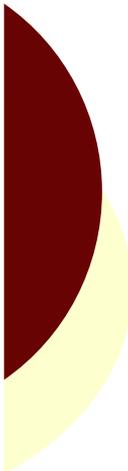


## Exclusivity and sublicenses

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- **Exclusive, sole, nonexclusive** license.
- Competition (nonexclusivity) can be good for the technology.
- Platform technology: best under nonexclusive licenses.
- Pharmaceutical Products: high risk and investment, exclusive license.
  
- **Reservations** and **exceptions**: existence of third party prior rights, or licensor keeps some activities (example: manufacturing).
  
- **Sublicenses**: only under good reasons. Means that the licensee does not have the resources to develop the technology.
- Alternatives to sublicenses: direct licenses!.

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## Field of use and territory

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- **Field of use**: try to divide the market and define carefully the Field of use to get the most out of your technology.
- Find the best partner for each possible application.
  
- **Territory**: world-wide makes little sense, find the best partner for each geographical area.
- Depends on the maturity of the technology.
- Licensing in different territories at different times, as technology evolves.
- Can set performance targets for each territory.

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## Considerations

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- Tool to allocate risks.
- **Initial License fee:** should reflect cost of transferring the technology, no its development.
- **Milestones:** For products with long development they use resources best allocated to the product.
- **Royalties:** needs clear definition of basis for calculations.
  - Complex royalties schemes.
  - “Cost of development” and other rebates.
  - Royalties for know-how or information.
  - Guaranteed minimum royalty.
- **Anti-stacking** and related provisions.
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## Performance, reports, inspections and audits

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- **Licensee performance:** product development, manufacturing, marketing, product promotion, regulatory.
  - Detailed product development program and timing. This needs clear assessment of state of technology.
  - Clear objective performance criteria.
  - Milestones and penalties for underperforming.
  - Curing provisions.
  - To control main risk: no performance and lock up of technology.
- **Licensee Reports:** tool to control performance.
- **Inspection and audits:** as a precaution to check that resources are allocated to the project. Important when royalties start to flow.

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## Know-how, new technology, grantback and options

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- **New developments and improvements:** ownership should be clearly spelled out. Problems of joint ownership of patents. Problems with inventions of more general application.
- **Grantback clauses:** assignment of new patents (where possible) or royalty free licenses to Licensor.
- **Option to license:** new or related developments.
- **Restraints of Trade:** problems of competing products and limitations to licensee (including R&D). Careful with antitrust regulations.

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## Patents: prosecution, maintenance, infringement, validity

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- **Prosecution:** control of patent portfolio, decision-making process, cost of prosecution, disagreements.
- **Maintenance:** in time and territory. First option for licensee to get ownership if licensor is no longer interested.
- **Infringement:** licensor and licensee right to sue, cooperation in infringement proceedings, sharing of monetary recovery.
- **Validity:** risk of losing patents in prosecution or infringement proceedings.
  - Consequences for the License agreement if patents found invalid?
  - License of know-how.

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## Representations and Warranties

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- **Right to grant license.**
- **Patents:** validity, ownership, due care, employee inventions.
- **Known liabilities:** known problems in the patents. In case of Universities for example list of disclosures by inventors.
- **Validity:** a clause that imposes an obligation on the licensee not to challenge the validity of a patent is illegal (Europe TTBE regulation, US: *Lear v. Adkins*). But there can be provision to define the conduct of the parties in such circumstances (i.e. termination by licensor).
- **Infringement of third party rights:** can never be warranted.
- **Negation of implications** by Licensor.

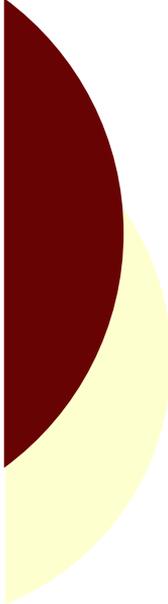
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## Term and Termination, disputes, law applicable

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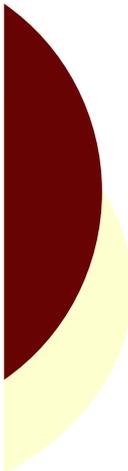
- **Termination:** when all rights and obligations of the parties expire (sequentially). Thus there is not a clearcut ending date.
- Set usually until **last to expire patent**, but some obligations such as confidentiality or accrued royalty payments continue.
- Termination by **non-performance**.
- Term under **Know-How** or **Trade secret** licenses: should be specified.
- **Disputes:** choice of law important in multinational agreements, arbitration provisions give a good solution. Curing provisions help avoiding litigation.

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# *TECHNOLOGY LICENSING AGREEMENTS: STUDY CASES*

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## **CASE 1: UNIVERSITY – New target for an important disease**

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- Professor Z has found a new receptor, inhibition of the receptor reverses a neurodegenerative process.
- The target has been validated with animal models.
- The University has filed a patent directed to the receptor, a screening method using it and to compounds agonists or antagonists of the receptor.
- Professor Z is about to retire and thinks he can make big money out of this!.

## CASE 1: UNIVERSITY – New target for an important disease

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### Licensor:

- University wants its research to benefit the public.
- Lacks resources to monitor infringement.
- Uncertainty about patent prosecution.

### Strategy:

- Grant non-exclusive licenses under generous terms.
- Alternative: set spin-off.
- Reach-through royalties?.

### Licensee: spin-off

- Small company to do initial screening and find compounds.

### Strategy:

- Get WW exclusive license with right to sublicense.
- Add value to the technology and then find a bigger partner or finance.
- Build up better IP position on the compounds.

## CASE 1: UNIVERSITY – New target for an important disease

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### Conclusions

- University has a weak position, infringement is difficult to monitor.
- Either it continues research (screening) or grants nonexclusive licenses to disseminate research and increase the chances a useful drug is found.
- if licensed to a Spin-Off, the licensee should try to keep ahead of competitors and build up a stronger IP position.

## CASE 2: Small Company- Drug Delivery System

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- A small company, NanoDD, has some basic technology about original colloidal systems (nanoparticles) that are good carriers of all kind of bioactive compounds. They are covered in a basic patent.
- In vitro and in vivo models show that the system increases and changes the bioavailability of the drugs, in some cases it is also specific, targeting the area affected by the disease.
- The company holds several patents and patent applications on improvements, different compositions of the colloidal systems and on targeted drug delivery.

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## CASE 2: Small Company- Drug Delivery System

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### **Licensor: divide the cake**

- Willing to spread the risk through several licensors.
- Wants to keep most interesting part (targeted DD) for own development.

#### Strategy:

- Find different licensees willing to develop the DD system for different noncompeting products.
- Opportunity for several royalty steams.
- Drug Products already on the market to avoid double risk.
- Keep improving IP position.

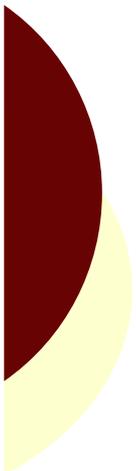
### **Licensee:**

- Generic or product at the end of life cycle.
- Opportunity for new revenue stream.
- Lower costs of development than for new drug.

#### Strategy:

- Good due diligence.
- Low initial milestones in view of risks and availability of alternative DD systems.

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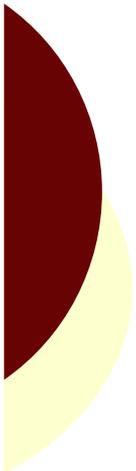
## CASE 2: Small Company- Drug Delivery System

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### Conclusions

- NanoDD has platform technology and should maximise its use through nonexclusive licenses.
- It is important that it keeps control and continue research to avoid dependance on R&D of licensees.
- Application of DD technology to generics avoid IP and regulatory issues of products still under development.

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## CASE 3: Medium sized company - product in clinical trials

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- Company DreamDrug has several products in its pipeline, all for CNS diseases. Based on an original approach, the products have shown excellent results *in vitro* and *in vivo* animal models.
- The most advanced product DD999 has finished phase I clinical trials in oral form and has shown no toxicity, ongoing phase II trials are showing activity in the disease.
- Company DreamDrug knows that the compounds in preclinical could be even better.
- Company DreamDrug lacks financial resources and knowledge to complete clinical trials for DP999

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## CASE 3: Medium sized company - product in clinical trials

### Licensor: long term view

- Willing to share control to speed up development
- Wants to strengthen its position
- Bet on the original approach rather than on the product

#### Strategy:

- Long term WW exclusive licensing and codevelopment agreement with big pharma.
- Make sure only DP999 falls under it.
- No options yet for rest of pipeline.

### Licensee: business opportunity

- Needs to fill the pipeline
- Business opportunity in view of financial problems of Dreampharma
- Interested in full pipeline

#### Strategy:

- Good due diligence, DP has risks.
- Offer tempting milestones
- Try to get control of newly generated IP rights
- Build relationship and try to get access to rest of DP pipeline.

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## CASE 3: Medium sized company - product in clinical trials

### Conclusions

- Exclusive Licensing seems the only possible approach, could be limited in territory.
- Good tailoring of patent issues in the agreement is important: still a long way before reaching the market and inventions specific to the product or more general can be made within the project.
- DreamDrug should improve its IP position over the “original approach” before the deal to make sure Licensee does not use its size to find alternative compounds outside its patents.

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## CASE 4: Small Company- Genetic testing

- Company GEN-TEST has found that GEN1 is involved in disease X and that people presenting a specific mutation in GEN1 are 30% more likely to develop disease X before they are 50.
- Disease X affects a significant proportion of the population so a diagnostic test predicting the incidence of the disease would be wellcome.
- Company X filed several patents covering GEN1 and its mutations, their uses and diagnostic methods based on them.

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## CASE 4: Small Company- Genetic testing

### **Licensor: tight control**

- Control the technology, aware of significance
- Further develop diagnostic tool
- Find new mutations

### Strategy:

- Negotiate licenses but to be the only to perform the tests.
- High prices
- Build up database and knowledge with samples being tested

### **Licensee: upset!**

- No way around patents
- Serious money due to population being tested
- Public health system needs to perform the tests

### Strategy:

- Challenge the patents
- In case of public health system threat of compulsory license

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## CASE 4: Small Company- Genetic testing

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### Conclusions

- A softer, non-exclusive approach would have been better?
- Public opinion can play a role even in these complex and technical issues.

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## Negotiating styles to be avoided

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India - Rajasthan - Jaipur - Snake Charmer

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Intellectual Property

**Thank you for your attention.**

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