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INTERNATIONAL CONGRESS ON INTELLECTUAL PROPERTY | ABPI

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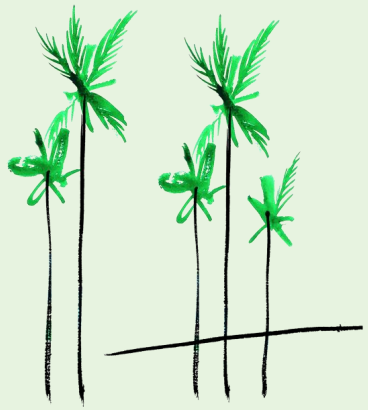


The Value Proposition of Pharmaceutical Patents

R. Craig Tucker
IP Patent Counsel - Eli Lilly and Company
– Regional IP Counsel for LATAM

NOTE: The purpose of this presentation is to provide educational and informational content and is not intended to provide legal services or advice. The opinions, views and other statements expressed by the presenter are solely those of the presenter and do not necessarily represent those of Eli Lilly and Company, ABPI or AIPLA.

Who are we??? The Pharmaceutical Industry?

Medicines

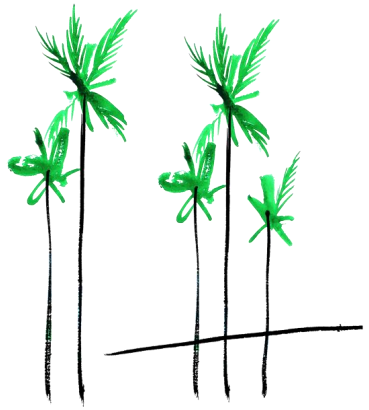
Better Health

Good when you are sick

Stuff at the pharmacy or hospital

Who are we??? The Pharmaceutical Industry?

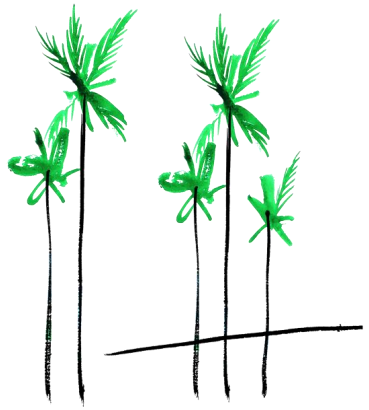
Innovators vs Generic Manufacturer



Who are we??? The Pharmaceutical Industry?

Innovators vs Generic Manufacturer

Distributors

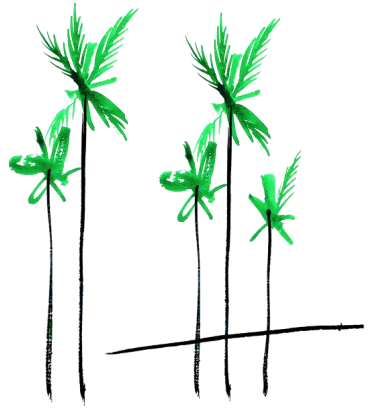


Who are we??? The Pharmaceutical Industry?

Innovators vs Generic Manufacturer

Distributors

Don’t forget we all serve Patients through Prescribers or over the counter



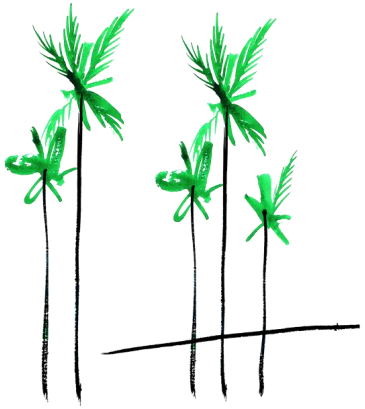
Based on education of Dr. or public

Who are we??? The Pharmaceutical Industry?

Innovators vs Generic Manufacturer

How are we portrayed?

vs



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Who are we??? The Pharmaceutical Industry?

Innovators vs Generic Manufacturer
How are we portrayed?

vs

How we like to view our selves

OR

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I propose a new view of all participants . . .

Conscientious

Gifted

Hard Working

Intelligent

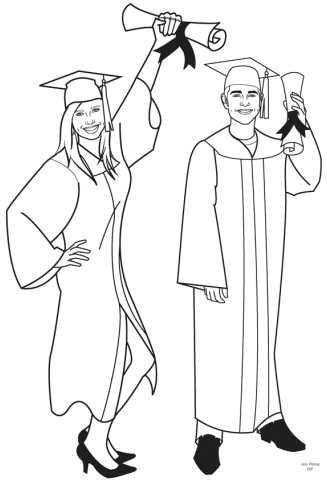
People Striving to earn
“Dignified Existence”

Helping others do the same

Through better health

. . . . With families we love and support . . .

. . . Within communities we all need to thrive . . .



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- So wherever someone is involved in the legitimate pharmaceutical industry, we can all be satisfied they are trying to make a living to bless their families and communities through economic prosperity while providing for the health needs of our fellows.

Innovator

Generic

- Let’s see how this can be done in the best way for everyone, both now and long term

So why the conflicts? . . . A modest proposal:

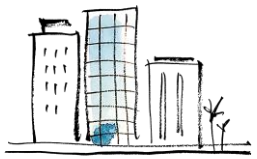
Who invents and develops a new (better) medicine?

Researcher
Developer
Market developer
Educator
Business people

Who manufactures and distributes a mature pharmaceutical product?

Process engineers and technicians
Analytical chemists
Distribution chain managers
Retail/hospital Pharmacists
Tending physician
Business people

What does it take for each to fulfill their role?



Who pays? and Who gets paid? (*Who should??*)

Patient
Insurer (Government)

Those who made it ***possible***
Those who made it ***available***

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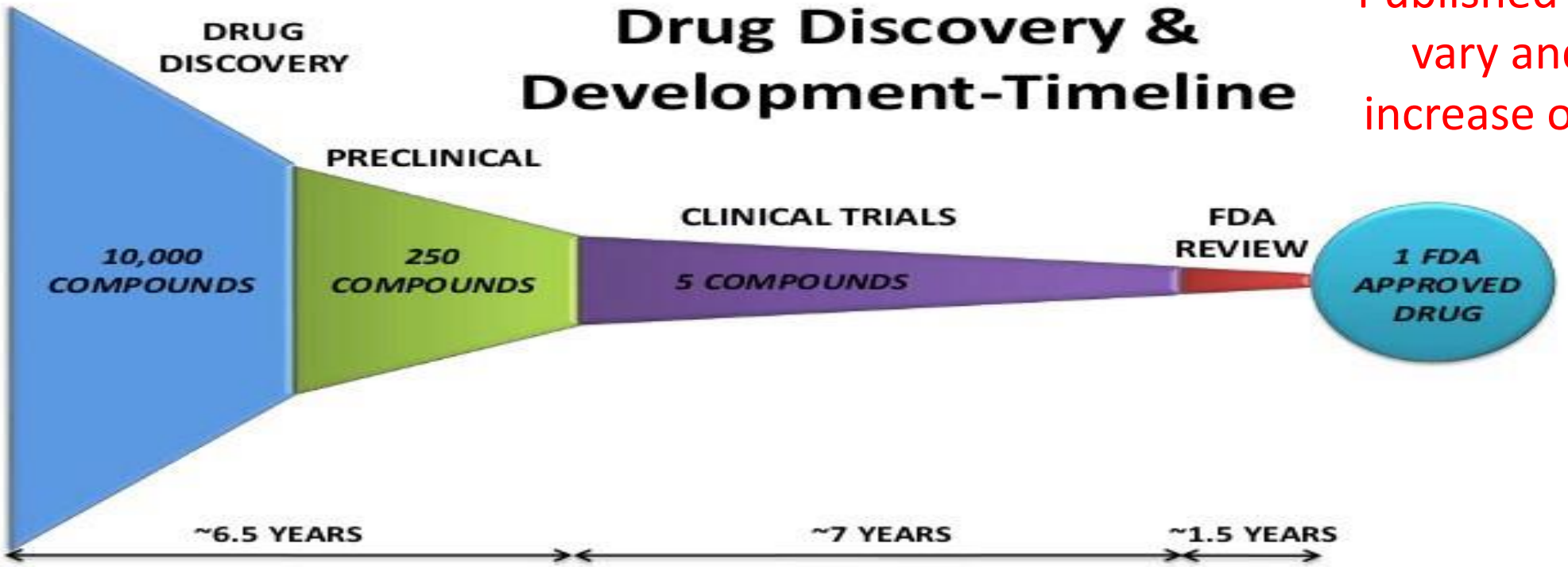
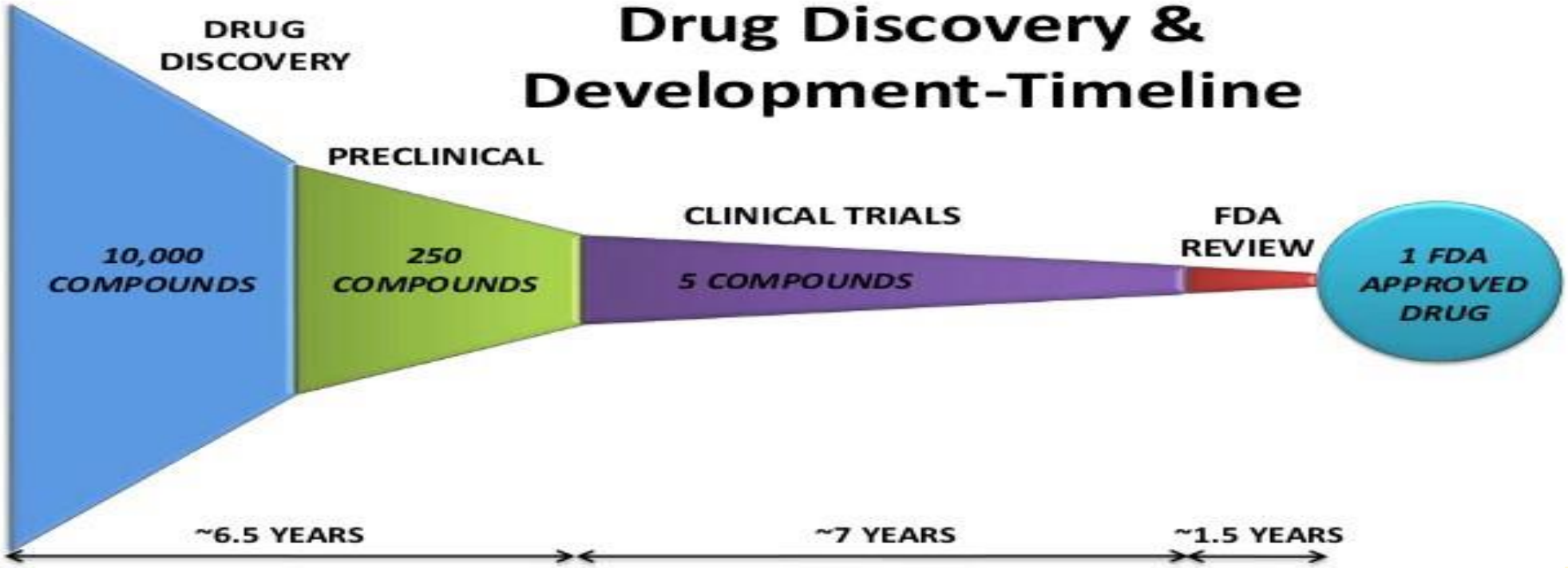


Published averages vary and have increase over time

Discovery: ~ 10-20% of costs, but significant permanent infrastructure required
Clinical: ~ 80-90% of costs for a 1 in 5-10 shot of achieving an approved product
Total: $1-1.5 Billion / $2-2.6 Billion for biologics
Time lines: 8-12 years / 10-15 years for biologics

Profitability: est. 2/10 gaining approval will earn more that the investment cost

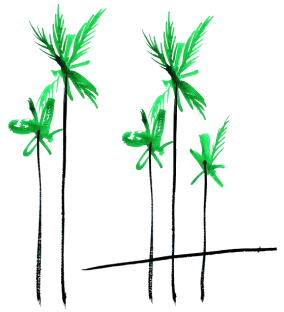


Total: $1-1.5 Billion / $2-2.6 Billion for biologics
Time lines: 8-12 years / 10-15 years for biologics
Profitability: est. 2/10 will earn more that the investment cost

Would you “roll the dice” with those odds?

With your money ???

Generic Drug Development Scenario



- Total Costs $0.7 – 2 million / $100 million & up for Biosimilars
- Time to approval: 2-3 years / 5-9 years for Biosimilars
- Profitability:
  - Already proven by Reference Drug
  - 70-90+ market penetration within 6 months in many countries

Published averages vary and have increase over time

- Development consists of
  - Developing manufacturing facility
    - 3 GMP lots for data for registration
  - Labs for quality control and maybe minimal clinical trial to show bioavailability compared to reference drug.
  - Distribution chain development and minimal sales force

Comparison Shows Why the Concern for IP

<u>Innovator Business</u>

- Dev. Costs: $1-1.5 Billion
  / $2-2.6 Billion for biologics
- Time to market: 8-12 years
  / 10-15 years for biologics
- Profitability: est. 2/10 will recover investment cost
- *Lose 70-90+% of Market when generic available*

<u>Generic/Biosimilar Business</u>

- Dev. Costs $0.7 – 2 million
  / $100 million & up for Biosimilars
- Time to market: 2-3 years / 5-9 years for Biosimilars
- Profitability: "Guaranteed" within typical market competition

NOW will you "roll the dice"??

Clear need for protection of new products

Abundantly clear that :

- **NO** new medicine or improved medicine will come into existence
- **IF NOT FOR** combining
  - Great talent and skill from a wide range of expertise
  - Facilities, materials, administration, and other resources
  - Sustained for a long period
- **IF** once successful, there will not be **subsequent cycles** of new medicines **IF** the **'critical mass'** is not maintained indefinitely
- **THUS** the investment **risk** that brings the new medicine should be **timely rewarded** to incentivize re-investment again and again.

Two Proven Methods to Allow Natural Flow of Reward to Generators of IP in Pharmaceuticals:

- Patents
  - Government granted
  - Limited time determined legislatively

    20 years from filing + adjustments for governmental delays in grant

    (minimum term guarantee, limited extensions for Patent &/or MA grant delay)
  - Dependent on ability to get Preliminary Injunction, and then win on merits
    - Requires notice of Generic MA with mechanism to obtain P.I. before launch
  - Damages do not compensate and recovery is too slow to fund next cycle of innovation

- Regulatory Exclusivity

  (Data Package Exclusivity)
  - Government granted

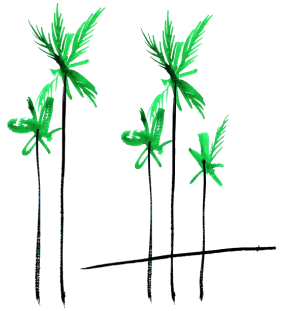
    Agency granting marketing rights
  - Limited time determined legislatively

    Ranges 5-12 years or more
  - Absolute with regard to generic market entry
  - Starts when innovator can market product
  - No risk of Damages if patent validity reversed

Benefits flowing from strong IP policies

- We've seen that to have hopes in brighter futures through new medicines for things not treatable/not effectively treatable, society must find a mechanism to reward the innovator for taking the risk that resulted in the present new drugs.
- We know that once developed, we'll have them available from then on, and expectation that once the patent/regulatory period has expired, their expense will go down to commodity levels.
- But the wait can be difficult when the budgets are always tight 'today', making it difficult to be patient .. . .
- **Is there other 'value added' from pharmaceutical patents ?? . . . .**

. . . . I mean other than preventing medical advance from coming to a grinding halt leaving our present day disorders uncared for??



Strong Patent Systems Promote Investment in New Technology, Including Pharmaceuticals

Two measure of impact of the strength of a patent systems have been Foreign Direct Investment (FDI) and Biopharmaceutical Competitiveness & Investment index (BCI):

- Strong IP laws have been seen to increase FDI. Reciprocally, increased FDI has been used as an incentive for developing countries to strengthen their IP laws. The Biopharmaceutical Competitiveness & Investment index (BCI) for Brazil has been in decline in recent years.
- Brazil scores behind Chile, Colombia and Mexico in terms of its overall IP Index Score in the life sciences industry, and it is reported that Brazil is losing foreign investment and innovative activities. In terms of FDI as a share of GDP, Brazil scores the third lowest among Latin American markets.
- Many studies show a significant positive correlation between strong IPR policies and increased economically beneficial innovation activities such as: FDI, domestic early research and clinical trial research, increased partnerships and academic collaborations, patent filings, increased employment, particularly in higher wage jobs.
- Developing Countries that implement strong IPR policies, are increasingly developing domestic innovative pharmaceutical industries. (e.g. China, Taiwan, Korea.)

Other Community Benefits:

- Innovative Pharmaceutical industry development in a country leads to new opportunities for graduate careers locally
  - Stops drain of national talent to foreign industry
- Higher paying jobs (commensurate with the investment in skills development required) support communities through higher tax base, more disposable income to use on consumer products, entertainment and services
  - Thus creating more jobs at ALL levels of education and skill in ALL business sectors in the community
  - Breeds greater levels of education, supporting continuous improvement in the communities
  - The greater education levels bring more innovation/patents in other industries as well, thus investment in strengthened Patent system leads to broad based growth, including exportable products and services.

A word about “Subsequent Innovation”

- Perception: Innovators use unfair patenting “tricks” to “Evergreen” their products - detriment to society

A word about “Subsequent Innovation”

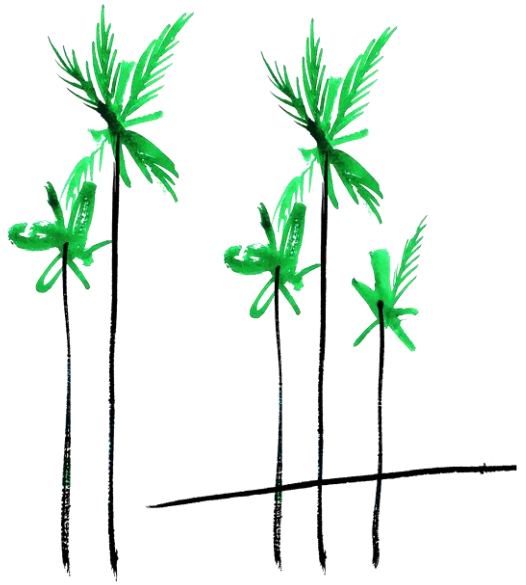
- Myth 1: Unfair ‘evergreening’ patent tactics are increasingly slowing generics to the market. . . . .

  - Truth: at least in the USA, the ave. patent exclusivity of innovator drugs has remained essentially constant at about 13.5 yr. since 1995.

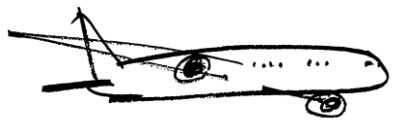
  - Truth: Generic Penetration accelerating
    Currently gaining ~ 80% within first 6 months

A word about “Subsequent Innovation”

- Myth 2: unfair tactics build “patent hedges” of multiple patents and this is somehow wrong. . . . .
  - Truth: Many industries obtain patents on various aspects of their products:
    - Titleist Pro V1x Golf Balls **60 patents**
    - BlackBerry KEY2 LE **242 patents**
    - Nike Flyknit Shoe Technology **300+ patents**
    - Firefly Light Up Timer Toothbrush **15 patents**
    - LG Spectrum VS930 Smartphone **626 patents**
    - Bose Quiet Comfort 20 & 20i Headphones **35 patents**
    - Honeywell Xenon 1900 Series Scanner **91 patents**

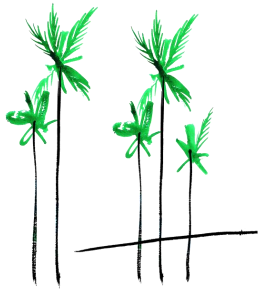


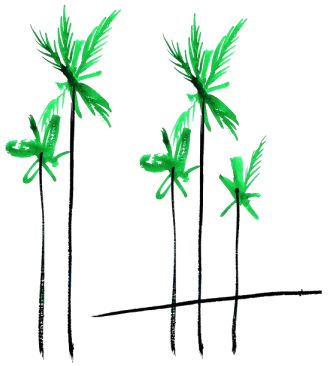
A word about “Subsequent Innovation”



- Myth 3: Somehow the subsequent innovation patent is invalid on its face and should not be enforced . . . Not really inventive

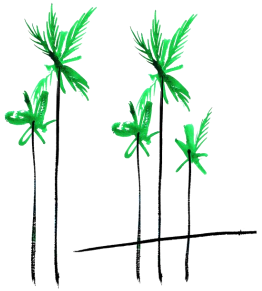
  - Truth: the patent office uses the **same standard** of novelty, inventive step and written description as any other industry’s subsequent innovation or multiple patents per product.

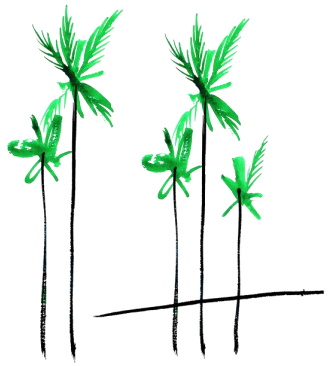




A word about “Subsequent Innovation”

- Myth 3: Somehow the subsequent innovation patent is invalid on its face and should not be enforced . . . Not really inventive
  - Truth: During the long development path, often there are road blocks that would block development of a promising compound from EVER coming to the market . . . Without subsequent innovation overcoming that technical problem in an inventive way, there simply would not be a new medicine to give the patient!



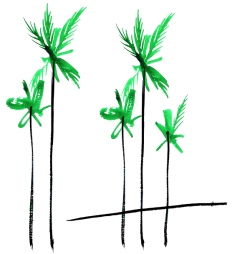


A word about “Subsequent Innovation”

- So why should the inventor be thought a “Cheat” or “Fat tycoon”, if he wants the benefit of his invention for the legal term?

- Why should a generic be allowed to enrich themselves off the newer invention, particularly in cases when the initial compound case has expired, so he COULD practice the expired invention?

- *Is it the regulatory hurdles??* . . . . Generic must invest to solve the technical difficulty in another way and prove equivalence with the reference drug to gain approval? Can’t just reference data?



A word about “Subsequent Innovation”

- **If** the invention **adds nothing** to the product, why must the generic copy it and not easily design around and easily prove equivalency?
- **Even if** the issue is the interplay with governmental regulatory approval scheme for generics,

  [the generic must the same API and ‘equivalent’ formulation, or provide data that the difference does not affect safety and efficacy]

  is not this public safety concern, which is also the driver for the industry’s exceptional development costs, even more persuasive that the value added by the subsequent innovation is worth the wait for all patents to expire
- Help the patent office do its job carefully to properly grant patents that are novel and inventive, then let the patent system provide the balanced incentive/reward to drive Brazil’s new economy

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Thank you for your time and careful consideration

"Reasonable Cooperation is always the better path,
Though it requires you to respect your competitor and listen"

Some references used

- Zuniga, P. et al. J. of Policy Modeling (2016) "Conditions For Innovation In Brazil: A Review Of Key Issues And Policy Challenges". Available at https://pdfs.semanticscholar.org/6fac/be4be9d991fbdcc32ea3bb949dd5d51b6255.pdf.
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