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A Global, Strategic Approach to Patent Prosecution

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Technical Minds. Legal Muscle.

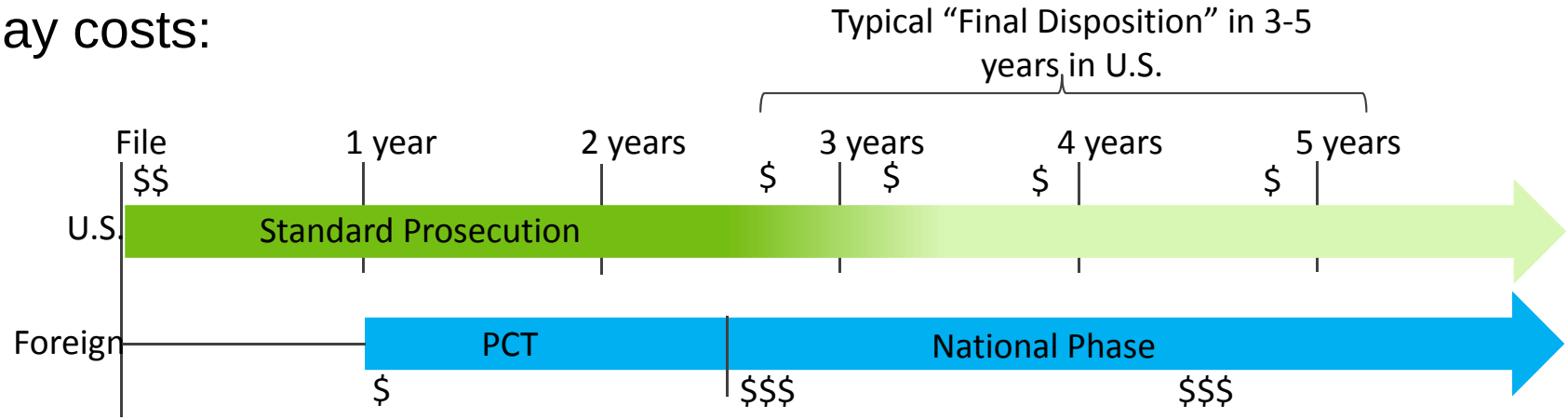
Agenda

- Traditional approaches to patent drafting and prosecution

- An improved global, strategic approach:
  - Drafting and filing
  - Prosecution

Traditional Patent Prosecution Paradigm

- Draft primarily with U.S. market in mind
- Delay costs:



- Freedom-to-operate was the primary concern
- Many start ups would avoid non-U.S. filings

Problems with this approach

- U.S. patent enforcement has become more difficult
  - Increased scrutiny from PTAB, § 101, § 112
- Heightened commodification (Third Industrial Revolution)
  - Big companies suck up the margins from their suppliers (e.g., automotive, smartphones)
- Long run costs are usually higher, given the inefficiencies of prosecution delays

Traditional Patent Prosecution Paradigm (Biopharma)

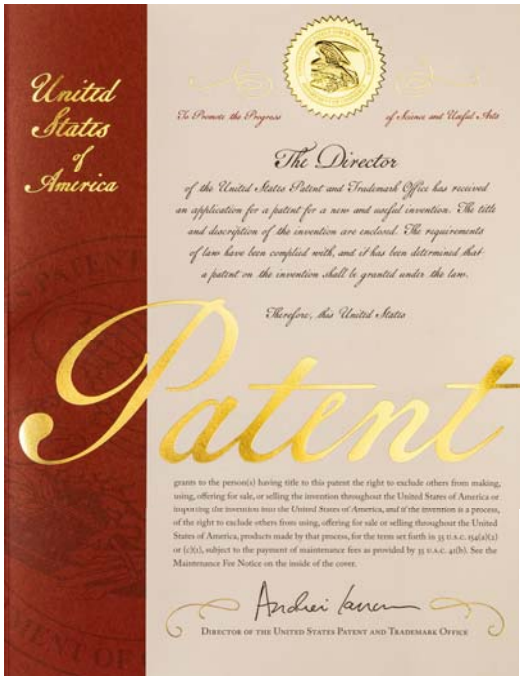
- Drafters of initial applications draft an application describing all possible variation and uses of compound or biologic such as:

-Indications

-Combination therapies

-Routes of administration

-Dosing regimens



-Salts

-Pharmaceutical dosage forms

-Purification methods

-Homologs and variants

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Traditional Patent Prosecution Paradigm (Biopharma)(cont.)

- Drawback: Guesses are often inadequate for continuations/WD&E but adequate for obviousness rejections
- For example, an earlier patent or publication with “estimated” dosing based on animal data may render obvious future dosing application from actual Phase II human data
- Or, adding recrystallization/purification steps in earlier patent or publication may then inherently anticipate a later Polymorph or purity application

Global, Strategic Drafting and Filing

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Drafting for eligibility across jurisdictions (non-biopharma)

- Describe the ***technological*** goals of the invention
- Describe the ***technological*** challenges faced by the invention, and/or the technological limitations of the prior art
- Describe how the invention achieves its ***technological*** goals and overcomes the ***technological*** challenges/limitations using ***technological*** features
- Include test data to show **improvement** over the prior methods
- Target for favorable art units (Art Unit 3600 has very low allowance rate, unlike Art Unit 2100)

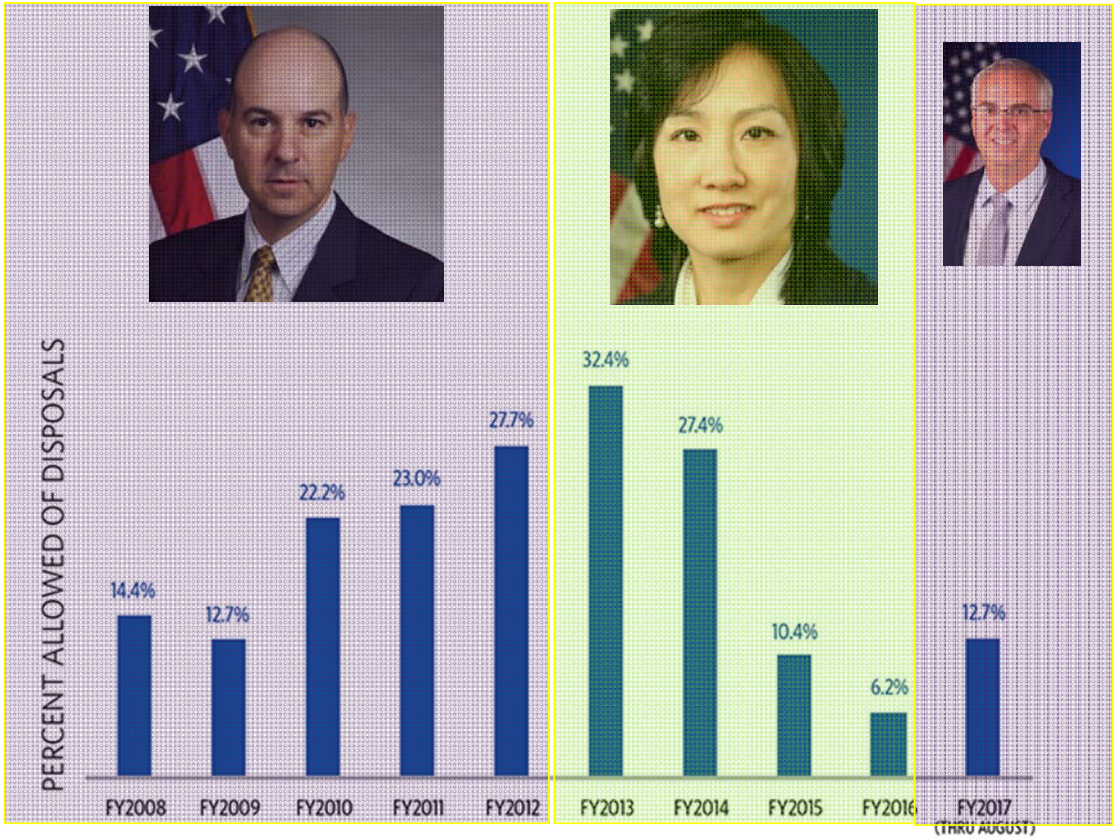
Drafting for written description support across jurisdictions (non-biopharma)

- Watch out for intermediate generalization problems in Europe
  - Consider drafting multiple dependent claims
- Europe, China require claiming “essential” features
- Use simple, easy-to-translate sentences
- In the context of software and electronics
  - Watch out for *Williamson* problems in the U.S., China
  - China requires disclosure of each “module”

Getting more pro-applicant for software claims?

Art Unit

3600



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Building an IPR-resistant portfolio

- Challenging validity after patent issuance at PTAB
- Large portfolios with many claims tend to be more difficult and expensive to challenge at the PTAB
- Specific claims with clear scope
- More description of advantages
- Consider
  - Including in prosecution history more description of distinctions of the prior art
  - Submitting evidence, such as expert declarations

Avoid over-disclosing (Biopharma)

- Patent term, patent term, patent term
- Manage patent lifecycle holistically
- Be very careful and precise in earlier applications to avoid creating prior art to be used against later applications
- Avoids § 103 rejections from your own work
- Extends expiration dates further in the future

Method of Use Patents (Biopharma)

- Often challenged at the PTAB
- Examiners likely to require “unexpected results” for allowance
- Need to develop invention’s story around approved indication
- What out for prior disclosures on clinicaltrials.gov or the EMA
- Consider adding pharmacokinetic parameters to claims
- Ideally, claims should match product label

Diagnostic Method Patents

- Patentable subject matter: what is/is not eligible subject matter?
- Divided infringement issues
  - Draft claims and application so steps are under control of a single actor
- SCOTUS Framework: *Bilski* (U.S. 2010), *Mayo* (U.S. 2012), *Myriad* (U.S. 2013) and *Alice* (U.S. 2014)
- *Fed. Circuit:* ***Ariosa*** *(2015)*: method steps well-understood, conventional and routine; ***CellzDirect*** *(2016):* claims directed to a new and useful lab technique for preserving hepatocytes; *and* ***Vanda*** *(2018):* claims directed to an *application* of the results of diagnostic testing

New Uses / Subpopulations

- Consider filing applications to sections of product label related to safety and efficacy
- FDA is likely to require same from generics
- Examples:
  - Discontinuing treatment if certain side effects observed
  - Decreasing dosage if certain side effect is observed or adding second active ingredient to treatment regimen
  - “Black box” warnings such as renal impairment
  - Dosing regimens and packaging to increase compliance or avoid abuse

Global, Strategic Prosecution

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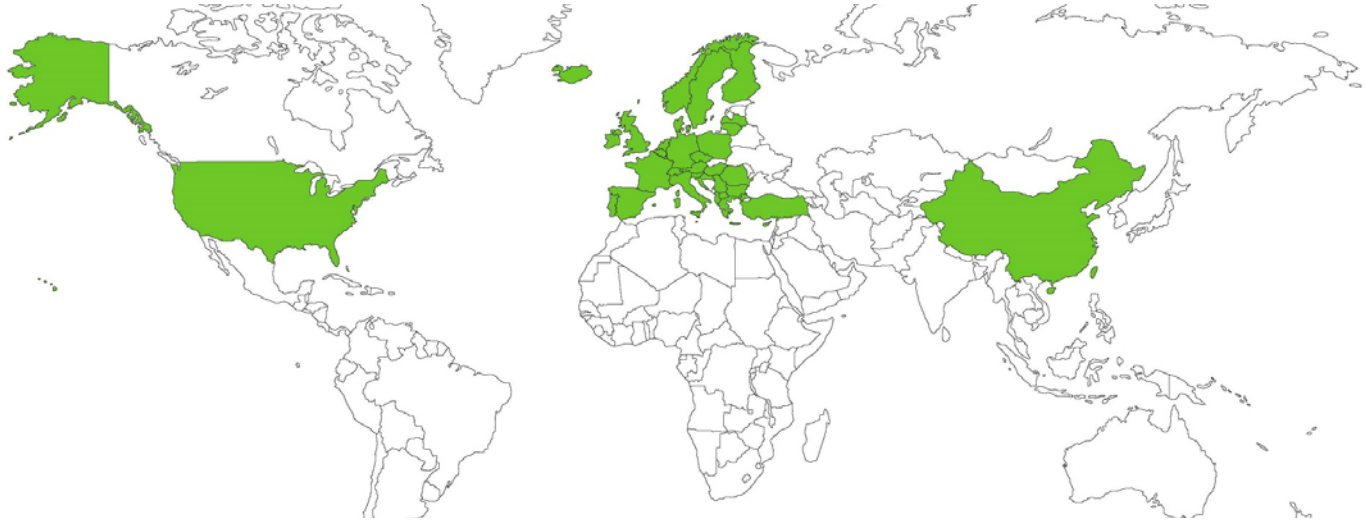
Consider your markets: Worldwide, but Efficient, Strategy



- U.S., Europe, and China are the three key markets
- Together, they comprise roughly 60% of global GDP

United States

- Despite headwinds against patent value in recent years, many see a correction taking shape
- Prediction: the Iancu-led U.S. Patent Office is going to make systemic changes that increase patent value both on the pre- and post-grant side
- Need an optimized U.S. patent, defensible at the PTAB and in district court litigation
- Software-related and medical diagnostic inventions present special problems
  - Consider availability of trade secrets and non-publication options

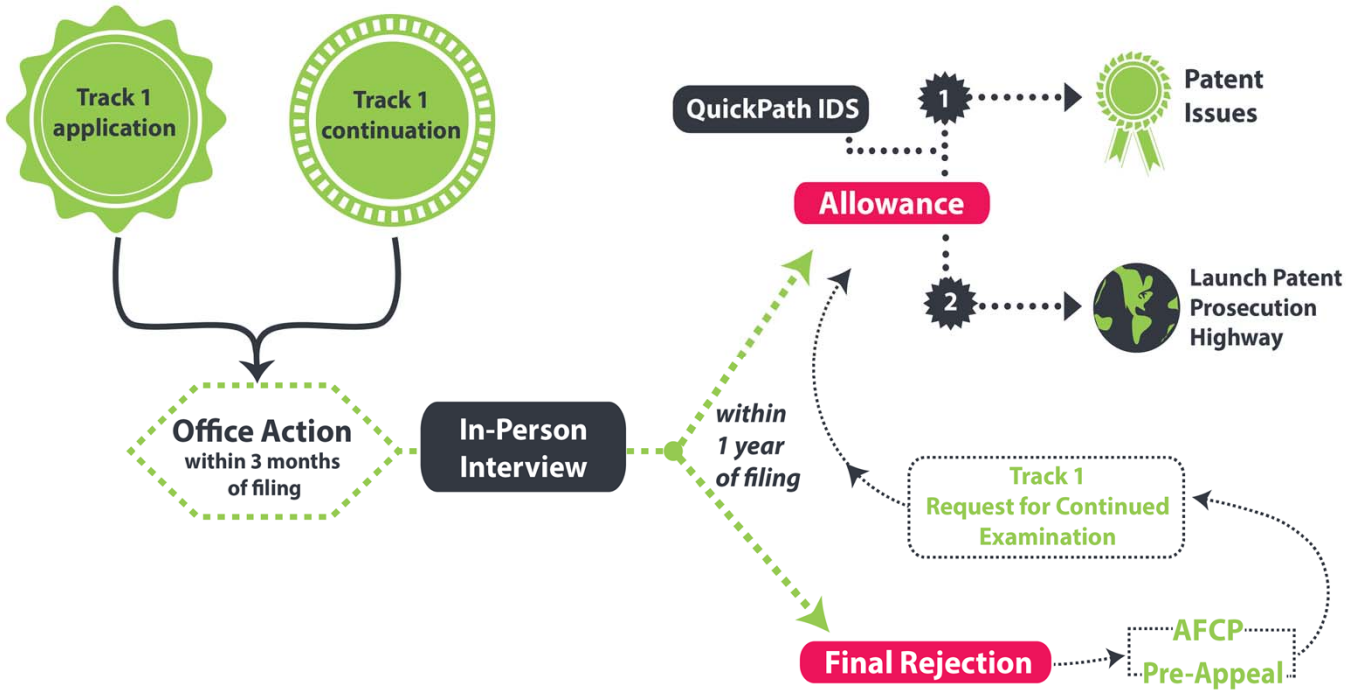
Europe

- EPO patent still available
- National patent offices also an option
  - (e.g., DE, UK, FR, etc.)
- For EPO and national route, choose countries carefully, because validation and annuity costs can accumulate quickly
- Unitary patent still on hold pending German litigation (and now Hungary too?)

How Companies Are Using Fast Tracks

- Fast Patent Portfolio Creation
  - Start Ups Seeking Investment
  - Shielding Against Known Competitors
  - Sword for Entry in New Space
  - Making Acquired Portfolios Relevant
- Create New Front in Patent Litigation
  - Patent Owners Augment Position
  - Defendants Increase Assets to Counter

Combining ways to accelerate in the U.S.



Use PPH to Go Global Quickly and Efficiently

Source: http://www.uspto.gov/patents/init_events/pph/index.jsp

PPH – Fast and High Grant Rates

PPH Statistical Data

	Office of Later Examination																			
	AU	CA	CN	CO	CZ	DE	DK	EA	GB	HU	IL	JP	KR	MX	MY	NO	RU	SG	TW	US
(a) Grant Rate [%]	100.00 (67)	89 (65)	- -	90 (57)	- (60.1)	- -	- -	- -	77.3 -	- (52)	100 -	82.0 (71.5)	80.9 (59.2)	99.07 -	100 -	- -	100 (78)	100*3 -	95.6 (77)	81.36*1 (68.65)
(b) First Action Allowance Rate [%]	64.1 (3.34)	33 (5)	- -	48 -	- (11.4)	- -	- (4)	- -	12.5 -	- (7)	85 -	20.2 -	17.6 (4.6)	71.03 -	97 -	- -	87.5 (25)	100*3 -	38.2 (7)	21.84*1 (12.91)
(c) Average Pendency from PPH Request to First Office Action [months]	0.46 (6.1)	0.8 (11.5)	2.7*1 -	4 -	- -	7.3*1 -	- (5.2)	2 -	1.2 -	- (13)	2.08 -	2.6 (9.3)*2	2.3 (11.0)	0.91 -	3 -	- -	3.09 (9.5)	2.7*3 -	1.65 (11)	7.28*1 -
(d) Average Pendency from PPH Request to Final Decision [months]	0.92 (18.44)	5.4 (31.2)	11.9 -	6.8 -	- -	- -	- -	- -	8.5 -	- (50)	2.4 -	7.3 (15.2)*2	6.2 (16.4)	2.92 -	6 -	3 -	3.45 (11.3)	2.8*3 -	5.91 (18)	19.11*1 -
(e) Average Number of Office Actions	0.38 (1.79)	0.9 (1.6)	1.0 -	0.5 -	- (1.12)	- -	- (1.04)	- -	1.20 -	- (1.34)	0.14 -	1.0 -	0.85 (1.02)	0.39 -	2.00 -	- -	1.68 (1.9)	0*3 -	0.65 (1.04)	2.98*1 (3.09)

From Jul. 2016 to Dec. 2016
Notes;

*1 Figures including PCT-PPH

*2 Period:Apr.2014-Mar.2015

*3 The statistics provided here do not include applications which are:1) pending examination; or 2) pending a response from the applicant to the first office action (except for the statistic on average pendency from PPH request to first office action).
( ) : All applications including PPH and non-PPH

Source: JPO website

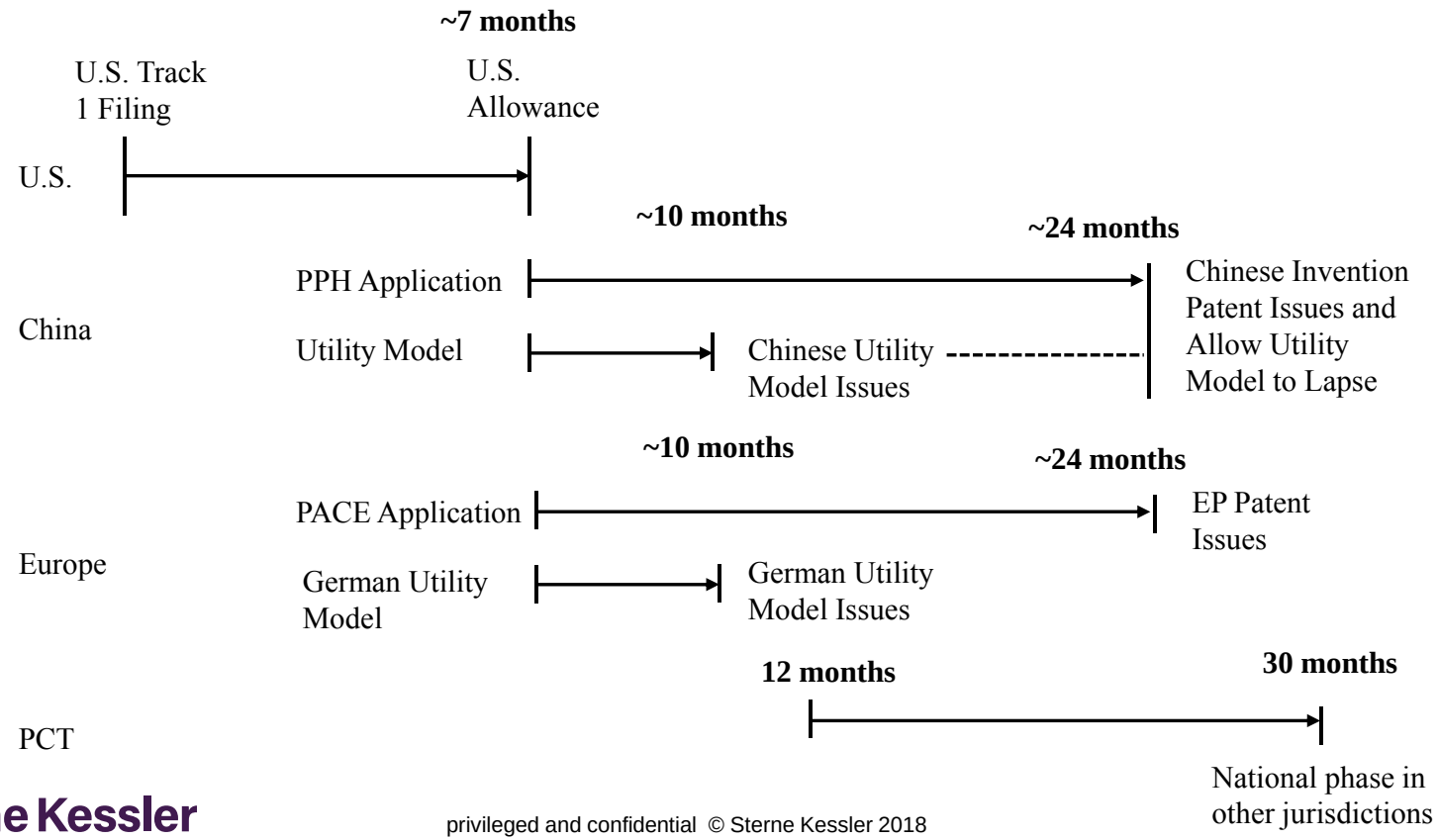
Utility models / Invention registration

- Fast, limited, or nonexistent examinations; low cost
- Can, in some cases, be used in conjunction with utility patents
- Don’t have the presumption of validity
- Usually shorter term – e.g., 10 years
- Usually limited to apparatus claims (i.e., no method claims)
- With some exceptions (notably, Germany), must be filed by the Paris Convention deadline
- Sometimes lower inventiveness requirements (China)

Design patents

- Utility patents protect the way an article “works” design patents protect the way an article “looks”; but NOT mutually exclusive
- Relatively narrow protection based on figures, more limited term
- Usually simple or no examination
- Renewed *Apple v. Samsung* award affirms their value in the US; by statute, entitled to disgorgement of profits from the “article of manufacture”
- Special international considerations – requirements vary from country-to-country
- GUI designs are booming in the US

Putting it all together—one possible approach



Toda Raba

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KPMG

Changes in the Tax World - Digital Economy and Intellectual Property

International Tax Department

KPMG Israel
July 2018

A Little Preview

Today's Agenda

- A little bit of history
- Changes in the tax world
- BEPS action plan
- Documentation requirements
- US tax reform
- What's next?

Once Upon a Time – Intellectual Property and Value Creation in the Past

The (Tax) World is Changing

חדשות כללי כללי

עוד מיליארדים לקופת המדינה? כחלון חתם על אמנת מס בינלאומית חדשה

אחת המשמעויות של האמנה היא שחברות ענק דוגמת מיקרוסופט, גוגל או פייסבוק לא יוכלו עוד, למשל, להפעיל מרכז פיתוח בישראל, ובמקביל להתחמק מתשלום מס על ידי רישום הקניין הרוחני המפותח בו במקלטי מס מחוץ למדינה

חגי עמית | התראות במייל
17:56 07.06.2017

ישראל לא ערוכה לעידן שאחרי תכנוני המס הגלובליים של התאגידים

OECD פירסם הנחיות הקושרות בין מקום הפיתוח של קניין רוחני למקום שבו הוא נרשם ■ כדי שחברות רב־לאומיות לא יעבירו את מרכזי הפיתוח שלהן מישראל, ועדת אנדורן המליצה להפחית משמעותית את המיסוי על הכנסותיהן מקניין רוחני - והגיע הזמן לאמצן

המדען הראשי מזהיר: האם החגיגה בהיי-טק עומדת להיגמר?

אבי חסון: "אנחנו קרובים לתקרת הזכוכית. אם לא נבצע את המהלכים הדרושים כעת, הם ייכפו עלינו"

גלי וינרב 16:02 ,22/08/2016

גלובס
זירת העסקים של ישראל

זהירות, אל תבריחו מכאן את החברות הרב-לאומיות

עו"ד רו"ח אסתר קורן 24/7/16

בתקופה האחרונה עובר תחום המיסוי מהפכה. אחת הרפורמות הבולטות ביותר היא מיסוי הכלכלה הדיגיטלית. תוכנית ה- Base Erosion and Profit Shifting Project, ובקיצור BEPS, היא פרויקט בינלאומי שמקדם ארגון ה-OECD בעידוד ארגון 20 המדינות המפותחות (G20). זאת, כדי להתמודד עם תכנוני מס בינלאומיים של חברות גלובליות המעבירות את רווחיהן לטריטוריות עם משטרי מס מיטיבים, ובמקרים רבים למקלטי מס שבהם לא מוטל מס כלל.

בלעדי לכלכליסט

מס הכנסה דורש מקוקה־קולה 150 מיליון שקל

רשות המסים הוציאה שומה לענקית המשקאות הבינלאומית עקב תמלוגים של מאות מיליוני שקלים שקיבלה במשך שנים מהזכיינית הישראלית. החברה צפויה לנהל מאבק משפטי מול הרשות

The New Player in Town - BEPS Action Plan

Action 1 – Addressing the tax challenges of the digital economy

Action 2 – Neutralizing the effects of hybrid mismatch arrangements

Action 3 – Strengthening CFC rules

Action 4 – Limiting base erosion via interest deductions and other financial payments

Action 5 – Countering harmful tax practices

Action 6 – preventing the granting of treaty benefits in inappropriate circumstances

Action 7 – Preventing the artificial avoidance of PE status

Actions 8 – 10 – transfer pricing aspects

Action 11 – Collecting and analyzing data on BEPS

Action 12 – Disclosing aggressive tax planning arrangements

Action 13 – Guidance on transfer pricing documentation and country-by-country reporting

Action 14 – Making dispute resolutions mechanisms more effective

Action 15 – Developing a multilateral instrument to modify bilateral tax treaties

Documentation of the (Business) Relationship

Description of services / product

Risk/Reward allocation

Transfer pricing mechanism

US Tax Reform and Its Affects on Intellectual Property Taxation

What's Next? - The New Questions to Be Asked

Where is the value of the IP created?

Where to tax the company?

How to tax the company?

Thank you for listening!

Itay Falb

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