



# Interviews

(From the Startup Perspective)

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## *Startups, Patents, and Interviews*



## *Startups*

Startups are innovation engines of the U.S. economy

Startups create new wealth (not a zero sum game)

In the next decade, many of the significant innovations in drugs and medical diagnostics (e.g., precision medicine) will originate in startups



## *The Long Reach of Startups*

Incubators

Inventors

SEC

Accelerators

Startup Employees

Banks

Angel Investors

Law Firms

Investment Banks

Venture Capitalists

Vendors

Patients

Universities

Consultants

Customers

USPTO

CLIA Labs

Major Corporations

FDA

Stock Exchanges

Federal and State Courts

## *Startups and Patents*

Startup companies in the diagnostic, drug, and medical device spaces live (and die) by their patents

Patents with claims of sufficient scope to exclude competitors are critical to obtain funding

Startups have high burn rates, and without periodic funding injections, startups languish or die

Startup patents must be of high quality, because the patents will be scrutinized in: funding rounds, IPO or sale, and associated diligences



Interviews are (often) *critical* to efficiently getting patents with claims of commercially relevant scope

*Interviews:*

A negotiation of the scope of allowable subject matter

Can be critical to getting to allowance

Can minimize prosecution and prosecution history estoppel

Can result in a faster allowance



## *Startups and Patents*

Patents reduce uncertainty for startup companies

Patents reduce risk for investors

Startups, for a variety of reasons, tend to avoid appeals

So compact, efficient, prosecution is important for startups





## *Interviewing: Preliminary Considerations*

*Examples of When to interview (timewise):*

Pre-first office action (e.g., Track 1 cases)

After a first or non-final Office Action

After a final Office Action (in some instances)

*Examples of Reasons to Interview:*

Early in prosecution, before both sides “dig in”

When prosecution has stalled

When the Examiner may have concerns that are not of record

When there seems to be a misunderstanding of law, fact, or both



## *Some Initial Considerations*

The most effective interviews occur when decision makers sit on both sides of the table

If an Examiner is not a Primary Examiner, therefore, we may ask for a SPE, QAS, or another Primary Examiner to also be involved in the interview

We do this for compactness of prosecution, not out of disrespect for any Examiner



## *Some Initial Considerations*

We also aim to be in a position to make decisions at every interview

For example, if we are proposing claim amendments, we have client approval to agree to go forward with those amendments if the Examiner indicates allowability (or a high likelihood of allowability)



## *Some Initial Considerations*

We know the record – including references - and are able to provide support for proposed claim amendments

We try to see things from the Examiner's point of view

If the Examiner suggests an approach, amendment or argument, we carefully consider if we could adopt and advance client interests



## *Other Issues: 101*

If the case is one in which 101 issues have been raised  
(usually a diagnostic but also some method of treatment cases)

AND

At least some claims do not map to examples in USTPO guidance

THEN

Consider asking for a 101 specialist to be present in the interview



## *Preference for In-Person Interviews*

Interviews can be in person or e.g., telephonic

When possible, we prefer to interview in-person

Thus, if we have a small delay in interviewing until a hoteling Examiner will be at the USPTO, we will generally wait and take the in-person interview





## *Preparation Ahead of the Interview*

We put significant time into preparing for interviews. This includes:

We know the record – including references and support for proposed claim amendments

We try to see things from the Examiner's point of view

- Try to “read between the lines” of the rejection(s)
- Some disconnects due to “broadest reasonable interpretation”

We simplify the issues *ahead of time*, if possible

- Dispose of easily-remedied defects/issues before, or early in, the interview

We focus on the most important facts

- stick to a few strong arguments/points
- time is limited, complexity is bad for an interview

We look for holes in our arguments, including possible weak spots

## *Consider Declaration*

Establish unpredictability by opinion, scientific reasoning and/or NPL reference showing different outcome or unpredictability

Secondary considerations- unexpected results, long-felt need, skepticism of others, etc.

- Inventor opine that when gave results at a conference, attendees expressed surprise
- Long-felt need- and references have been in public domain for a number of years

# *Interview Request & Agenda*

## *The Interview Request*

- We submit as early as possible to allow for any scheduling delays
- We prefer to call the Examiner about an interview – a personal connection
- Alternative new on-line Automated Interview Request Form (AIR)
  - ▶ While it is still preferable to call examiner directly, in situations when the examiner is not responsive to an interview request this may be a good tool to use

## *Agendas*

We provide agendas (and where appropriate, draft amended claims) in advance of the interview

If we think we can effectively argue that the pending claims distinguish over the art, we may prepare, but hold back, amended claims as a plan B



## *The Interview*

## *The Interview*

Clear-up easy issues (112's, etc) first

We respect the Examiner and others at the interview

‘Business to be conducted with decorum and courtesy’ (37 CFR 1.3)

It is good interview practice, and we work towards building a productive long term relationship with the Examiner and the USPTO

## *Interviews*

Interviews allow for clearer communication

Examiner's may have concerns that are not of record

We try to elucidate these during the interview

Examiners have limited time for interviews

We aim to keep each interview as concise as possible

We spend interview time in proportion to the importance of the issue

For example, we would devote more time to an obviousness rejection than an antecedent basis issue

## *Data in Interviews*

In some instances, we may have data that support e.g., a claim of a superior and unexpected result

If the Examiner has not seen the data, interviews are a great place to introduce the data and gauge the Examiner's response (e.g., would overcome the *prima facie* case or appears to be a difference in degree rather than kind)

## *Consider a Declaration*

Declarations strengthen arguments and push toward allowance

- Evidence (actual data) strongest but even opinion declarations have value
- Cannot be ignored- *In re Kao* (Fed. Cir. 2010)
- Ups ante, Examiner needs authority to refute
- Challenge interpretation of reference made by Examiner- expert opinion
  - ▶ Expert would interpret teaching differently





## *Inventors and Interviews*

When appropriate, we will include an inventor on the interview team

Inventors can help explain the importance of the invention

Inventors may have more credibility than attorneys who can be viewed, in some instances, as making mere attorney arguments



## *The Interview: Listening*

### *We listen very carefully in interviews*

Often the Examiner will say things in an interview that are more important than anything the Examiner will put in writing

Understanding the Examiner may lead to successful prosecution even if the interview doesn't lead to allowance

We welcome suggestions from Examiners regarding claim amendments or other actions that may place the claims in condition for allowance



## *Conducting the Interview – Seek Clarity*

We ask questions:

- “Could you explain the rejection, I simply do not understand it”
- What’s the Examiner’s real concern?
- What evidence might the Examiner consider persuasive?
- What amendments might the Examiner consider sufficient to overcome the rejections?

## *Words Matter*

We use words that resonate with Examiner

- Not predictable

- No reasonable expectation of success

We avoid words that have lost favor

- No teaching, suggestion, or motivation to combine- wasted argument

The same argument can be framed in different ways- we choose the one more likely to succeed

- Not predictable and no reasonable expectation of success

## *101 Issues*

When possible, we try to map claims to USPTO guideline examples

Participation by a 101 subject matter expert can be helpful

Area remains in flux with recent Board decisions invalidating method claims for 101 issues



## *Interview Summary*

We do not, as a rule, pressure Examiners to state in an interview summary that claims are allowable (although we are happy if that is the case)

Claims may require further search and analysis

Arguments may require further consideration

## *Interview Summary*

We generally ask that interview summaries be kept at a high level e.g., arguments or amendments were presented which may advance prosecution

Interviews can reduce prosecution history estoppel

But this has been mitigated somewhat by the recent USPTO efforts to make e.g., proposed claim amendments presented in the interview, of record

## *Missed Interviews*

Rarely, an Examiner will miss a scheduled interview

In our experience, these misses are for good reasons (e.g., sick child needing to be picked up from day care)

Generally, we do not call the Examiner's SPE in these instances. Rather, we work with the Examiner to reschedule the interview.





## *Unproductive Circumstances*

Rarely, life events happen suddenly and unexpectedly (e.g., loss of a family member)

If a life event happens shortly before an interview, out of respect for the Examiner, we will reschedule the interview



## *Post Interview*

## *Post Interview*

We timely communicate our impressions of the interview to clients, as well as, where appropriate, indications that claim amendments would likely place the claims in condition for allowance

We also timely submit interview summaries, having the appropriate level of granularity, to the USPTO

Some firms have internal databases that track experiences with Examiners. Those firms would also update their databases.



## *“Real Life” Examples*



## *First Example*

## **Mycosis Fungoides (MF)**





MF is treated with nitrogen mustard (WWI chemical weapon) applied topically to the skin

Earlier treatments required e.g., dissolving NM in water or ethanol (which starts to inactivate the NM) and is difficult to apply in a focused manner

A startup had a gel-like composition for treating MF that was premixed, easy to apply, and stable, and did not produce a greasy feeling upon application



Interviews were a key part of building a patent portfolio around the composition and its use

The patents, in turn, allowed for investment and funding of clinical trials, and submission of a new drug application (NDA) to FDA

The drug formulation is now FDA approved and being used by MF patients





## *Second Example*



In an interview to discuss claims drawn to a pharmaceutical formulation and a coating for the formulation, the Examiner expressed the opinion that coatings, as a general category, were not patentable. This was not presented anywhere in the Official Action.

The client was present at the interview

The client agreed to cancelling claims to the coating and the Examiner agreed to allow the formulation claims

The formulation has now been FDA approved



## *Third Example*



A case covering an FDA approved pharmaceutical formulation received a final Office Action

In an after final interview, the Examiner indicated that specific claim amendments would place the case in condition for allowance

The client agreed to the claim amendments and the case was allowed

These patents were timely listed in the Orange Book, and provided protection against generics



## *Fourth Example*



We proposed to present claims in an interview excluding an element from the claims

The Examiner received the claims in advance of the interview, called us, and was concerned that we lacked support for the exclusion because the element was only positively recited.

We pointed the Examiner to MPEP 2173.05(i)

During the interview, the Examiner agreed we had support for the exclusion and that the claims would be allowable

## *Conclusion*

Interviews can be a powerful tool to advance prosecution

Generally, you get out of interviews what you put into interviews

Always treat the Examiner with respect, and try to see things from the Examiner's point of view



Thank You!

Questions?