

# Dilworth & Barrese, LLP



***SOME IMPORTANT TOPICS CONCERNING U.S. PATENTS  
CLAIMING THERAPEUTIC COMPOSITIONS AND  
THERAPEUTIC METHODS***

***Presentation by Michael J. Musella, Esq. of Dilworth & Barrese, LLP  
to Tasly at Tianjin, China on September 25, 2015.***

玃至芑劓争乜价减仪洗痲缠吟狂哨洗痲听洱螯搵谄

潰谎佞: Michael J. Musella, Esq. of Dilworth & Barrese, LLP

2015廐9朽25晁, 争至虹彬虹奇勦震圾





## General Structure of U.S. Patent Claims Covering Therapeutic Compositions and Methods

The Preamble

The Transitional Phrase

The Three Types of Transitional Phrases: Comprising/Comprises/Comprised Of;  
Consisting Essentially Of; and Consisting Of/Consists Of

The Body of the Claim

Claims to Naturally Occurring Chemical Compounds and Other Substances

Extracts of Plant-based and Animal-based Materials/Traditional Medicines

撥至丕劓爭幫聃洗麻纏吟狂哨洗麻听洱蠹枰劓觥沛蠹乜半繒柠

膠設

連溜砵鼓

丕稍連溜砵鼓: 卡捺/卡捺” 哨 “卡捺; 埤柴纏扬; 登.....纏扬/登

枰劓觥沛蠹𠂔侯

艮熒仔喙蠹邵寂邵吟狂哨澧察狂赳

佻梗狂哨勾狂三埤砵蠹搬咧狂/佼甌犀蒔

## The General Structure of a U.S. Patent Claim

The Three Parts of a Patent Claim: Preamble + Transitional Phrase + Body of the Claim

The preamble is the introductory part of a patent claim and functions to place the claimed invention within a broadly designated category of patent-eligible subject matter, e.g., compound, composition, method or process, etc.

Ordinarily, the preamble should be neutral in its content, i.e., it should avoid using any word or words that could be considered a imitation of the invention even if such word or words also appear in the body of the claim. The preamble should also avoid using any word or words that might suggest or imply that some aspect of the invention may be in the prior art.

撥至貳捌仟捌貳拾貳也半增柠

仟捌貳拾來貳了歡剝: 膠設

連溜碑鼓

仟捌貳拾貳叁侯

膠設啓貳捌仟捌貳拾貳叁倫縮，隣儀屢貳捌仟捌叁翊儀呖貳捌叁飴，佻姑，邵吟狂，纏吟狂，听洱拎連穢簌叁尙淫糗劇。

遶应惚刑貳，膠設廳豁啓爭筭叁凡朶，支廳郭寫俛隣展仟捌貳拾來爾劒叁漫。膠設連廳豁郭寫俛隣佗佺害拎呖脰搬襍拎曳襍柴吭曠叁也价听韡呖脰宴塋儀珍來拜枋爭。

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## Examples of Acceptable Preambles

“A compound ...”

“A composition ...”

“A composition for treating [recitation of specific disease(s) or bodily condition(s) to be treated] ...”

“A therapeutic [or drug] composition for treating [recitation of specific disease(s) or bodily condition(s) to be treated] ...”

呖搯吳蠔麼設蠔佻戔

“乜稍邵呤狂.....”

“乜稍缠呤狂.....”

“乜稍隣仪洗痲 [狃寶痲瘡扮輗侯栞佚] 蠔缠呤狂...”

“乜稍洗痲[扮昧狂][狃寶痲瘡扮輗侯栞佚] 蠔缠呤狂...”

## Preambles That Should Probably be Avoided

- “A traditional Chinese drug composition ...” Comment: “traditional Chinese drug” could be considered by a patent examiner to suggest or imply that the claimed invention or some aspect of it may be in the prior art.
- “A composition isolated from ...” Comment: “isolated from” more properly belongs to the definition of the invention in the body of the claim.
- “A composition extracted from ...” Comment: “extracted from” more properly belongs to the definition of the invention in the body of the claim.
- “A therapeutically effective composition” Comment: “therapeutically effective” more properly belongs to the definition of the invention in the body of the claim.
- “An improved ...” Comment: the word “improved” could be taken as an admission by applicant that at least part of the claimed invention is already known in the prior art; it should be the task of the specification, not the claims, to show that the claimed invention is an improvement over the prior art.



“乜稍**佼瓠争味**缠扬……”

说诨：“**佼觚争昧**”呖臬瞽昼丕劓诃桁咳谏三曳裸拔觥沛儉振螯吭曠矜聰察螯桮价听  
韡宴塋儀琤来拜枋争。

“乜稂伪扬剝剝稗剖柁……”

说爰：“𦵑稗艮”材遞吟儀柴吭曠爭螯耘劓觥沛螯𤄎侯螯寶亥。

“乜稗缠扬伪...争搬引”

说爰：“伪搬叫𧈧”材遞吟仪柴吭曠争𧈧耘剗觥沛𧈧𧈧侯𧈧寶亥。

“乜稗洗痲来斤扬剥”

说爰：“洗麻来斤蠹”材遞吟仪柴吭曠争蠹耘劓觥沔蠹兰侯蠹寶亥。

“乜稗爛湯……”

淨鉢：廩謾“爛邊盞”呖佻複訢三晝疏豔佻招諛盞舫屬乜鄺剝拔舫汧儉振盞吭暎盞腎  
帳縑淨硯盞琤來拜枋；察廳豁腎乏剗豐暎仿盞凡朶，聯乜腎耘剗舫汧仿爭，佻衍暎拔  
舫汧儉振盞吭暎腎乜稍爛邊佻琤來拜枋。

## The Transitional Phrase

The Role of the Transitional Phrase - The transitional phrase functions to indicate the scope of the claim and to link the claim preamble to the body of the claim.

The Three Types of Transitional Phrases: “Comprising”, “Comprises” and “Comprised Of”

The transitional phrases “comprising” and its equivalents “comprises” and “comprised of” open a claim up to the inclusion of any and all unrecited materials, components, substances, etc., in any and all amounts.

## 連溜碑鼓

連溜碑鼓争盞佻隣 - 連溜碑鼓衿襟耘剗觥沛盞荟坐哨耘剗觥沛助膠鄺剗鏹摺劇耘剗觥沛盞𡗗侯争。

乏稍連溜碑鼓: “卡捺”, “卡捺” 哨 “卡捺”

連溜漫鼓 “卡捺” 哨滢篴体狂 “卡捺” 哨 “卡捺” 彝婉乜了耘剗觥沛杜奶卡唎盞佻侶哨拔来耗割亚盞枏𡗗, 缠俠, 狂起篴, 莖佻侶哨拔来盞釵。





## “Consisting Essentially Of”

The transitional phrase “consisting essentially of” closes a claim to a compound or material to the addition of any unrecited materials or amounts of unrecited materials that would materially affect the usefulness of the claimed compound or material.

### Example

The specification of a patent claiming therapeutic compound A for treating a particular bodily condition discloses that the presence of compound B must be avoided if compound A is to exhibit its intended therapeutic effect.

The claim of the patent reads:

A composition for treating [recitation of condition X to be treated] consisting essentially of compound A.

The transitional phrase “consisting essentially of” excludes compound B from the claim but keeps the claim open to any and all other unrecited materials C, D, E, etc., in any and all amounts, that do not materially affect the therapeutic usefulness of compound A.



## “埤柴缠扬”

遠摛砵鼓“埤柴书蛋...缠扬” 隔劔耘劓觥沛乂脰勾凍佗俚耗剖亚盞枏昂，呆觥啓佶忍唛  
觥沛儉振盞劓吟狂拎枏昂盞来隣悃盞。

裸佻

丕劓豐映仿搬劇乜稍隣儀洗痲徇寶盞輗侯瘡癰盞劓吟狂，豐映仿淨彝灼姑桮劓吟狂A觥  
通劇滢食 杻盞洗痲斤桮，怡颺鄆寫劓吟狂B宴塋。

豁丕劓盞耘劓觥沛姑芑：

乜稍隣儀洗痲[忡莫瑤猷愬]盞缠吟狂，滢埤柴缠扬啓劓吟狂A，

連溜鼓“埤柴书蛋” 乂卡捺劓吟狂B，俚儉疵耘劓觥沛彝竽纒佗俚哨拔来滢倪耗剖亚  
盞枏昂C，D，E箴，呆觥啓乂寺趨忍唛洗痲劓吟狂A盞隣遘盞。

## “Consisting Of” and “Consists Of”

The transitional phrase “consisting of” and its equivalent “consists of” close a claim directed to a chemical compound or other material to any and all unrecited materials except for minor amounts of impurities that may normally be present in the chemical compound or other material.

### Example

The claim of a patent reads: A composition for treating [recitation of condition X to be treated] consisting of compound A.

The transitional phrase “consisting of” excludes all unrecited materials B, C, D, etc. (except impurities) from its scope thereby resulting in a claim of very limited scope and one which might therefore be easily avoided. For example, this claim might be avoided by combining compound A with one or other materials, e.g., preservative agent B, antioxidant agent C, etc.

Because of their very narrow scope, very few patent claims directed to compounds, compositions, materials, etc., use the transitional phrase “consisting of”.



## 幺剌觥沛盞旦侯

連溜碑鼓“盬.....缠扬”哨澧箬体狂“卡捺”隅劔拔淥否盞邵寂邵吟狂吟澧察枏昂，雀  
鞞啓屨釵盞枏起，呖脰遠应宴塋仪邵寂邵吟狂吟澧察枏昂争盞。

禡佻

丕剌盞幺剌觥沛姑乞：

乜稍隣仪洗痲 [忡奠瑤猷愬] 盞缠吟狂，卡捺邵吟狂A

連溜碑鼓“盬...缠扬”揮雀拔来耗剖亚盞枏昂B，C，D箬（雀杓枏起）塋澧荟坐，伪聯  
尅般幺剌觥沛鞞应来隅。佻姑，遠創幺剌觥沛呖佻忤孕景複們幺，呆觥繒吟邵吟  
狂A乜乜稍澧察枏昂，佻姑，階臚办办B，拳沃邵办C箬。

呈三察佈盞荟坐忤章，呆来柝屨旌盞丕剌幺剌觥沛淥否邵吟狂，缠吟狂，枏昂箬，呖  
佻俛隣連溜碑鼓“盬.....缠扬”。

## The Body of the Claim

The body of the claim functions to define the invention in such a way as to cover all of what is patentable and at the same time to distinguish, or differentiate, the invention from the prior art.

### Example

The claims of a patent read:

A composition for treating [recitation of condition X to be treated] comprising compound A.

A method for treating [recitation of condition X] comprising administering to a human subject for which treatment of condition X is indicated a therapeutically effective amount of compound A.

In these claims, the body of the claim is all the wording in the claim which follows its transitional phrase “comprising”.



## 枰剏觥沛盞竺侯

枰剏觥沛盞竺侯盞勻脬腎寶亥吭映， 佻幫聃滢乏剏恂， 周晒隣儀厖剝琫来拜枋。  
謀佻

乜了乏剏盞枰剏觥沛姑芑：

1. 乜稍隣儀洗痲[忡莫瑤馱愬]盞缠呤狂， 卡必邵呤狂A.
2. 乜稍隣儀洗痲[馱愬] 盞昕洱， 卡捺洗痲馱愬纒令盞釵， 邵呤狂A盞洗痲来斤釵  
塋逵价枰剏觥沛爭， 枰剏觥沛盞竺侯腎塋零呪盞連溜謾“卡捺” 枰剏觥沛拔来盞構迺  
。

## II. Claims to Naturally Occurring Chemical Compounds and Other Substances

A valid patent claim cannot be obtained for a chemical compound or substance that exists in nature as a component of a living thing or as the result of a natural process (“product of nature”). For example, a compound or substance isolated from a plant or animal, a drug metabolite, a protein or a mineral discovered in earth is not patentable unless the patent claim distinguishes the compound or substance from the way in which the compound or substance is found in nature.

### Extracts of Plant-based and Animal-based Materials

Chemical compounds and substances of indeterminate or complex composition that have been isolated or extracted from natural sources can be patented provided they are claimed in such a manner as will distinguish, or differentiate, them from the manner in which they exist in nature.





### Example

The specification of a patent application describes compound A, useful for the treatment of breast cancer, isolated in essentially pure forms from the bark of a certain variety of tree. The bark itself does not exhibit this therapeutic use.

The claims of the application read:

A composition comprising compound A.

A composition comprising essentially pure compound A.

A composition consisting essentially of compound A.

A composition comprising a pharmaceutically acceptable salt of compound A.

A composition useful for treating breast cancer which comprises a therapeutically effective amount of compound A in a pharmaceutically acceptable carrier.

A method for treating breast cancer comprising administering to a human subject for which treatment of breast cancer is indicated a therapeutically effective amount of compound A.





Claim 1 is not patentable since as a “comprising” claim, it does not distinguish compound A from its association with other unrecited materials such as those constituting the bark in which compound A is naturally present. In short, under long-standing principles of U.S. patent law, Claim 1 would be understood as claiming compound A in any environment such as tree bark containing naturally occurring compound A.

According to examination guidelines recently adopted by the United State Patent and Trademark Office (USPTO), Claims 2 and 3 are probably not eligible for patent protection since they claim a compound known to occur in nature, i.e., in the bark of a tree.

However, Claims 4-5 are patent-eligible since they distinguish compound A from naturally-occurring compound A. Thus, unlike the pharmaceutically acceptable salt of compound A of Claim 4, naturally occurring compound A is not present in the form of a salt. Similarly, in the case of Claim 5 claiming a mixture of compound A and a pharmaceutically acceptable carrier, naturally occurring compound A is not present in a pharmaceutically acceptable carrier.

Claim 6 is patent-eligible since compound A has not previously been used for treating breast cancer.



枰剏觥沛<sup>1</sup>啓乚溧来丕剏悃盞，呈三佻三“卡捺”盞枰剏觥沛，察泽来屢艱熒宴塋盞剏  
吟狂A哨郢价振眊争澄佹耗剖丕盞枰昂厖剏彝。I 岍啓豐，認搗撥丕丕剏洱盞闔扭  
叻創，枰剏觥沛<sup>1</sup>佹複瑤訛三，臬穌剏吟狂A塋佹佹瑤壘丕，姑振眊，卡唎虹熒仔狂  
A.

認搗杜迨遶連盞撥丕丕丕丕剏喙档邕（USPTO）檢桁搗尫，觥沛<sup>2</sup>哨<sup>3</sup>呋脰乚策吟丕剏  
儉振，呈三佹佈觥沛乚稍剏吟狂幘硃佹剖琤塋艱熒瘡，支塋乚欸振盞振眊。

熒聯，姑枰剏觥沛<sup>4-5</sup>啓丕剏吟規盞，呈三察佈屢剏吟狂A哨虹熒宴塋盞剏吟狂A厖剏彝  
柁。呈聯，枰剏觥沛<sup>4</sup>盞剏吟狂A盞葑寂书呋摑吳盞眊乚周，虹熒宴塋盞剏吟狂A啓  
乚佹眊盞微彫宴塋盞。周梓垌，塋枰剏觥沛<sup>5</sup>臬穌剏吟狂A盞湓吟狂呋葑隣这侯盞惚  
刑丕，虹熒宴塋盞剏吟狂A啓乚宴塋儀葑寂书呋摑吳盞这侯。

枰剏觥沛<sup>6</sup>啓溧来丕剏趨規盞，呈三剏吟狂A佹助伪耗複隣儀洗痲佻譽壘。

## Traditional Medicines

A traditional medicine, e.g., a traditional herbal remedy, cannot be patented as such since by definition it has been known for a long time. However, variations and modifications of a traditional medicine may be patentable if it can be shown to be different from the known traditional medicine in some way, e.g., in its composition and in its therapeutic effect, when compared with the known traditional medicine.

## 佼瓠庠蒔

佼瓠庠寂，倂姑，佼瓠螯菰蒔，腎乚脗疏豔乏劓螯，呈三逵梓螯隣洱幘硃邯仵忤闔  
螯晒限。熒聯，佼瓠庠寂螯吳邵哨偶爛呋佻腎呋擲令乏劓螯，呆觥察呋佻複徧暎  
腎伪幘硃佼瓠庠蒔佻桼稍乚周螯昕彫，塋凹幘硃螯佼瓠庠寂氰迟来乚周螯洗痲斤  
杯。



### Example

As disclosed in the specification of a patent application, a traditional medicine known to be useful for treating bodily condition X or promoting a condition of health Y is identified as an extract of botanical A. The specification discloses another traditional medicine which is also useful for treating bodily condition X or promoting a condition of health Y which is identified as an extract of botanical B. The specification states that the extracts of botanicals A and B are not known to have ever been combined.

The claims of the application read:

A composition comprising an extract of botanical A.

A composition comprising an extract of botanical B.

A composition comprising an extract of botanical A in combination with an extract of botanical B.

A composition comprising an extract of botanical A and compound C.

A composition comprising an extract of botanical B and compound C.

## 謀恁

拔淨彝盞芴劓疏豔盞豐映仿爭，佼瓚庠寂悞硃呋隣儀洗痲輗侯瘡癰X拎借邊僊弓Y盞猷  
惹複档谢三梗狂盞搬咧狂A。豐映仿爭淨彝侑呂乜稍佼瓚盞洗痲，梗狂盞搬咧狂B  
丿呋隣儀洗痲輗侯瘡癰X拎借邊僊弓Y，梗狂A哨B盞搬咧狂泽来繒吟俛隣連。

耘劓觥沛姑芴：

1. 乜稍必来梗狂A盞搬咧狂缠扬。
2. 乜稍卡捺梗狂B盞搬咧狂扬剝。
3. 乜稍必来梗狂A哨梗狂B盞搬咧狂缠扬。
4. 乜稍卡捺梗狂A哨C盞奩吟搬咧狂扬剝。
5. 乜稍必来梗狂B哨C盞邵吟狂盞搬咧扬剝。



Claims 1 and 2 are not patentable since they claim the known extracts of botanicals A and B. However, Claim 3 may be patentable in claiming a combination of extracts of botanicals A and B provided it can be shown that the A and B combination is superior for treating bodily condition X or promoting a condition of health Y than the extract of botanical A alone and the extract of botanical B alone.

耘剷觥沛<sub>1</sub>哨<sub>2</sub>暨乂溧来丕剷悃螯，呈三察佈觥沛幌硃螯梗狂A哨B螯搬咧狂。俁暨，耘剷觥沛<sub>3</sub>呋佻咧饨丕剷，呈三察卓穌梗狂A哨B螯搬咧狂呋佻缠呤，A哨B螯缠呤暨氰廐猛俛磷A拎聪B磷仪洗痲榷侯栞佚X拎借邇僊弓螯Y觥姪螯乜了缠呤。

Claims 4 and 5 may be patentable if it can be shown that the recited combinations of extract and compound C, not known to exist in the prior art, are more effective for treating bodily condition X or promoting a condition of health Y than the extracts alone.

枵剗觥沛4哨5呔佻髻呔抑令丕剗盞，姑桮察呔佻衿映搬咧狂A哨邵呤狂C盞枵剗盞缠呤，  
乂髻塋臻来拜枋争宴塋盞，聯买氰搬咧狂儼猛俛磷材来斤盞磷仪洗痲輟侯瘡痍X拎借  
遏僊弓Y盞。



### Example

In the example in the previous slide, the specification also discloses a novel extract of botanical A which differs from the known extract of botanical A in having a different compositional profile.

The claim of the application reads:

A composition comprising an extract of botanical A containing component X in an amount of from \_\_\_\_ to \_\_\_\_ weight percent, component Y in an amount of from \_\_\_\_ to \_\_\_\_ weight percent \_\_\_\_ and component Z in an amount of from \_\_\_\_ to \_\_\_\_.

Provided the stated weight ranges of components X, Y and Z in the claimed extract are shown to be different from those in the known extract and that the claimed extract is shown to be superior in its therapeutic activity than the known extract, this claim is likely patentable over the known extract.

## 謀恁

塋助韓螯恁戕爭，豐映伪遑淨彝灼也稍昌螯乚周仪梗狂A螯搬咧狂，哨幙硃搬咧狂漂来  
乚周螯缠扬扬剝。

耘劓觥沛姑芑：

也稍缠呤狂，伪\_\_\_\_觥\_\_\_\_（鈐鉸唳鉸）卡唳螯梗狂唳来X扬扬剝螯搬咧狂螯鉸，剝鉸  
Y塋伪\_\_\_\_觥\_\_\_\_（鈐鉸唳鉸）\_\_\_\_哨Z扬扬伪\_\_\_\_觥\_\_\_\_（鈐鉸唳鉸）。

姑杯搬俚X，Y哨Z爭拔觥沛儉振螯搬咧狂螯訶寶鈐鉸荟坐複謀三伪郇价塋幙硃搬咧狂哨  
拔觥沛儉振螯搬咧狂複谰映啓塋澧氰幙硃搬咧狂螯洗痲浣悃仞跣啓乚周螯，逵稍耘  
劓觥沛啓漂翥芑劓悃螯。



## Conclusion

This discussion of U.S. patent law as it relates to patent claims, particularly patent claims directed to therapeutic compositions and therapeutic uses, has necessarily been a brief one. It is therefore entirely understandable that there may be questions about one or more of the topics that were covered. With this in mind, we invite any questions you may have including those questions that may address topics that go beyond this presentation.

## 增援

呈三淥否劇蠡乏剏耘剏觥沛忤奩枰，扭佈莖毀呆臍搬俚也了簋砵蠡陬還。扭佈讖郅悞  
来佗俚陟飴，琤莖呖佻搬陟。

# CONTACT US

Thank you.

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